

INSTRUCTIONS FOR USE

# STARRSED INVERSA INSTRUCTIONS FOR USE

Version 1.10 MRN-144-EN



Master Registration Number: MRN-144-EN





# RR Mechatronics

Masters of Measurement

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Issued by the Support Department of Mechatronics



## Document history overview

MRN-144-EN

Published date 10 March 2015

Issue No	Date	Revised Section(s)	Changes	Authorised
1.10	March 2015	All	<ul style="list-style-type: none"> <li>General safety instructions</li> <li>Explanation of documentation</li> <li>New display illustrations</li> <li>Introduction of QC procedure</li> <li>Addition of maintenance level information</li> </ul>	H. Schavemaker
1.9	August 2013	Inversa Keyboard Trouble shooting Error list Appendix	<ul style="list-style-type: none"> <li>Single result added</li> <li>Air bubbles</li> <li>Error 20 and 70</li> <li>WI-404 rev. 002</li> </ul>	H. Schavemaker
1.08	January 2013	Inversa Keyboard	<ul style="list-style-type: none"> <li>Waste sensor to end user part</li> <li>Waste bottle alarm</li> <li>Protocol R-3500</li> </ul>	H. Schavemaker
1.07	April 2012		<ul style="list-style-type: none"> <li>Modifications in User interface</li> </ul>	H. Schavemaker
1.06	August 2011	Inversa Keyboard	<ul style="list-style-type: none"> <li>Minor changes throughout manual, explanations added for user interface.</li> </ul>	K. Artz
1.05	May 2011	Introduction, Glossary	<ul style="list-style-type: none"> <li>Line "The used sedimentation pipettes are automatically washed and dried" removed</li> <li>Explanation IVD added</li> </ul>	K. Artz
1.04	February 2011	Work instruction 401 Appendix	<ul style="list-style-type: none"> <li>Removed check waste pump tube condition from WI 401</li> <li>Appendices added: Tube connections, factory settings, maintenance schedule</li> </ul>	H.E. van Dijk

**Document history overview**


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1.03	January 2011	All	<ul style="list-style-type: none"> <li>• Replaced Key card for Chip card</li> <li>• Attention markers for User, Supervisor and Technician Included in menu descriptions</li> <li>• </li> </ul>	H.E. van Dijk
1.02	November 2010	Inversa Keyboard	<ul style="list-style-type: none"> <li>• </li> </ul>	H.E. van Dijk
1.01	September 2010	New version Error list	<ul style="list-style-type: none"> <li>• Menu options added</li> </ul>	H.E. van Dijk
0.00	August 2010	All	<ul style="list-style-type: none"> <li>• Manual started</li> </ul>	H.E. van Dijk

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## 1. INTRODUCTION

The **Starrsed Blood Sedimentation Rate Instrument** (hereafter called Starrsed Inversa) is an in vitro diagnostic medical device that automatically carries out the erythrocyte sedimentation rate analysis according to the **Westergren** method, conforming to CLSI approved standard H02-A5, using closed sample tubes filled with citrate or EDTA blood.

The Starrsed Inversa is an advanced ESR system that offers many unique features and benefits over the traditional ESR procedures. Automating this method has the following advantages:

- The Westergren pipettes are always filled to the correct level.
- Using closed sample tubes reduces the possibility of contamination for the user and environment.
- Standard glass Westergren pipettes are used, in which the measurement can be corrected to a constant temperature (18 °C Celsius). Even small abnormalities can be detected over a longer period of time, irrespective of where and when the blood sample was taken.
- Every sedimentation measurement is directly linked to an identified sample, so that a manual work sheet is unnecessary. Patient ID errors are reduced to a minimum by using the bar-code reader.
- In the EDTA mode, the accuracy of dilution of EDTA blood with citrate is considerably better than manual dilution achieved either by "tipping off" or using evacuated blood collection tubes pre-filled with citrate solution.
- The data can be send to your Lab Information System.
- Minimum sample volume is 1.2 ml for the Starrsed Inversa.
- The Starrsed Inversa can use a variety of closed tubes from different manufacturers.

### 1.1. Explanation of available documentation

Manuals for the Starrsed Inversa are available on three levels: for the operator, the supervisor and the service engineer.

The following manuals are available:

1. Instructions for Use (IFU)  
Intended for the operator: Contains instructions for normal operation, safety, preventive maintenance and trouble shooting procedures to solve the most common problems. Available in several languages.
2. User Manual (UM)  
Intended for the lab supervisor. Contains information from the IFU and additional information concerning settings, service, higher maintenance levels and trouble shooting procedures to solve more complicated problems. Only available in English.
3. Service Manual (SM)  
Intended for trained service engineers. Describes maintenance, servicing and repair of the instrument in detail. Contains detailed descriptions of parts, assembly drawings, modifications, extended trouble shooting, flow diagrams etc. Only available in English.

#### 4. Installation Manual (IM)

Intended for trained service engineers. Contains instructions and procedures for installation and start-up. Only available in English.

Manuals are available in PDF and HTML-format and can be downloaded from <http://www.rrmechatronics.com>.

## 1.2. Starrsed line of ESR instruments

The Starrsed line of ESR automated instruments is unique by the fact that it has automated the Westergren Method and fully complies with the published reference method, including working with diluted EDTA blood. The Starrsed line offers several types of ESR analyzers. Our solutions range from tube-based to rack-based to track-based, the latter resulting in the highest level of automation possible. Laboratories that operate different Starrsed instruments in different capacities are assured that correlations are precise and fully reliable.

Starrsed ST, Starrsed RS, Starrsed RL and Starrsed ST are instrument names of RR Mechatronics. Until 2014 the Starrsed ST was called Inversa 24M, the Starrsed RS was called AutoCompact, the Starrsed RL was called Interliner. RR Mechatronics changed the product names to benefit better from the worldwide recognizability of the brand name Starrsed.

## 1.3. Dilution principle

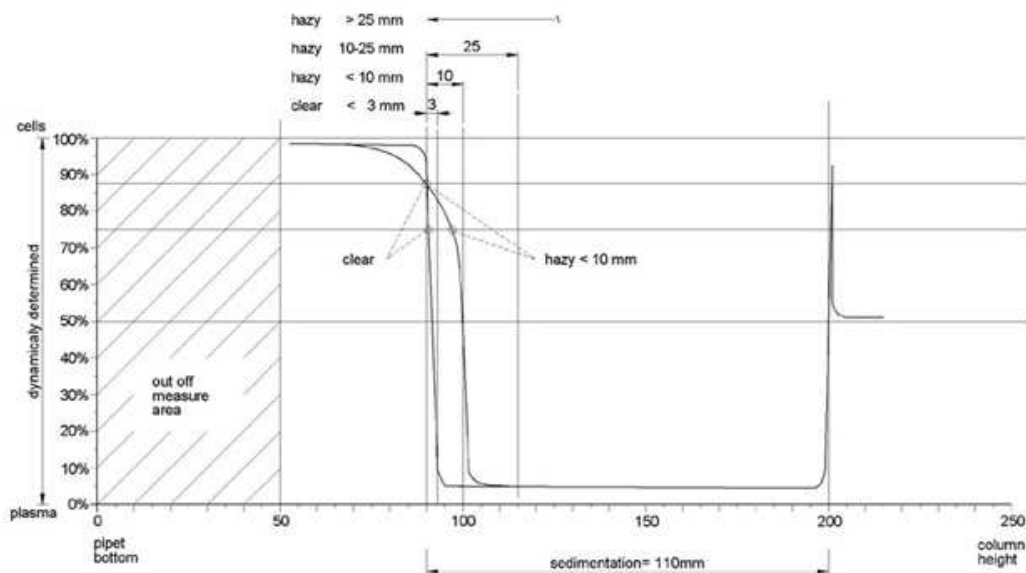
When the Starrsed Inversa is operating in the EDTA mode, the blood sample is diluted with sodium citrate during the aspiration process. On the Starrsed Inversa, the dilution is achieved through a mechanical link between the syringe on the diluter and the pipette piston. The dilution ratio is 4 volumes blood + 1 volume sodium citrate diluent; accuracy  $\pm 3\%$ .

## 1.4. Sedimentation measurement principle

The automatic reading of the Westergren sedimentation pipettes is carried out by moving an optical sensor along the pipettes. While the sensor is moving, a reading is made every 0.25 mm. The sensor is reading the absorption of infra red light through the Westergren pipette filled with blood. From these readings, values at a number of absorption levels are determined. All absorption figures are relative to the darkest and lightest reading (darkest = 100 % and the lightest = 0 % absorption respectively).

By definition the levels are:

87.5%	Cells/ plasma separation
75.0%	Hazy detection
50.0%	Meniscus detection



Graphic showing typical absorption values of a sample

## 2. INSTRUMENT DESCRIPTION

The **Starrsed Inversa** is a semi-automatic ESR instrument. The blood sample tubes must be mixed externally before they are loaded into the sample holder one at a time. The instrument can be configured to work with pre-citrated samples (Citrate mode) or with EDTA anticoagulated samples (EDTA mode).

The sodium citrate dilution takes place in a 4+1 ratio and is achieved with  $\pm 3\%$  accuracy.

Twenty-four Westergren pipettes are housed in the carousel. Each is of precision bore glass.

The fill line is back-flushed with sodium citrate diluent.

Positive sample identification is achieved with a barcode-reader and takes place before aspiration of the sample.

The temperature is corrected to the standard value of 18°C and ESR's may be read after one hour or 30 minutes. A predicted one-hour result is presented in the 30-minute mode.

Results of the test are expressed in millimeters and printed on the build-in printer.

The **Starrsed Inversa** can be interfaced bi-directional with Laboratory Information Management Systems (LIMS) through interface protocols developed by Mechatronics.

The main features of the Starrsed Inversa are:

- Single unit with small footprint, housing all units and containers.
- Closed compartment with a carousel holding 24 precision bore glass Westergren pipettes, measuring unit and pipette filling station.
- Build-in printer.
- Chip card system.
- Barcode reader for sample identification.
- Serial / parallel interface.
- Easy accessible keypad with light key pressure due to piezo technology.
- Battery backup memory.
- Accessories kit.



## 2.1. Chip card system

The Starrsed Inversa uses a chip card system which makes it possible to employ the instrument either in a pay-per-test scheme or on customer-owner basis. Specific types of chip cards also grant access to specific instruments settings.

A chip card must always be present in the card reader to operate the instrument.

The card reader is located on the left side of the Starrsed Inversa. Insert the chip card into the card reader with the printed side facing forward. The chip card is correctly inserted when it appears as shown in the picture:



### 2.1.1. Chip card type A to E

Chip cards of the types **A** to **E** are used to operate the instrument in a pay-per-test scheme. The chip cards contain a certain amount of credits units. How many tests can be performed with this amount of credits depends on the configuration which is made by the local Starrsed Inversa dealer. The following amounts of credit units are available:

Card type	Credit units
A	100.000
B	500.000
C	1.000.000
D	5.000.000
E	10.000.000



**NOTE:**

Available card types and amount of credit units per card may be subject to changes.

The total amount of credit units on the chip card is transferred to the Starrsed Inversa at once and the chip card is then rendered void. It is not possible to use the same chip card to transfer credits to more than one instrument.

This type of card is dealer dependent. The instrument only accepts chip cards of the dealer to which the instrument is configured.

### 2.1.2. Chip card type Q

Chip cards of type **Q** are used to operate the instrument in ownership without credit limitations and can only be used on instruments which are configured to accept the **Q** chip card.

### 2.1.3. Chip card type S

Chip cards of type **S** ("Supervisor card") are used by lab supervisors to grant them access to important instrument settings. When this type of chip card is inserted in the card reader, a PIN code must be entered to unlock the protected menus.

### 2.1.4. Chip card type T

Chip cards of type **T** ("Technician card") are used by service technicians to install and prepare the instrument for routine operation and to perform service functions. When this type of chip card is inserted in the card reader, a PIN code must be entered to unlock the protected menus.

## 2.2. Technical specifications

Technical specifications for the Starrsed Inversa:

### Starrsed Inversa instrument models:

Model	Model name	Catalogue number
	<b>Starrsed Inversa 24M</b>	<b>BANG109000</b>

### ESR method:

<b>ESR method</b>	Westergren method
<b>Temperature compensation method</b>	R.W. Manley: J. clin Path (1957), 10, 354
<b>30 minute method</b>	R. Rogers: Medical Laboratory World 1994
<b>Allowed blood specimen types</b>	<ul style="list-style-type: none"> <li>• For EDTA mode: Whole blood with &lt; 1% EDTA anticoagulant.</li> <li>• For Citrate mode: Whole blood (4 vols.) with sodium citrate anticoagulant-diluent (1 vol.)</li> </ul>
<b>Automatic dilution</b>	4 vols. blood + 1 vol. sodium citrate diluent (3.2% NaCl); accuracy $\pm 3\%$
<b>Reported result</b>	mm after 1 hour

### Reagents:

<b>Reagents used</b>	QRR 010931 Diluent QRR 010946 X-Clean
----------------------	--

### Blood volume:

<b>Aspirated blood volume per sample</b>	1.2 ml in EDTA mode 1.4 ml in Citrate mode
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**Sample tube types:**

<b>Sample tube types</b>	Most commonly used brands/types. Closed tubes with concentric cap only.
	<ul style="list-style-type: none"> <li>• Total length: 73 ... 93 mm</li> <li>• Body diameter: 11.5 ... 15.5 mm</li> <li>• Cap diameter: 13 ... 18 mm</li> </ul>

**Barcode reader:**

<b>Barcode reader type</b>	CCD.
<b>Reading capabilities</b>	Most common barcode labels
	Code39, ITF, Industrial 2 or 5, CodaBar,
	EAN/UPC and CODE128.

**Data storage:**

<b>Storage medium</b>	Battery back-up memory
<b>Storage capacity</b>	Results and raw data of 896 samples

**Starrsed Inversa power requirements:**

<b>Mains voltage</b>	115 - 230V AC	50-60Hz
<b>Fuse (20 x 5 mm)</b>	Slow blow 230V	1.6 Amp
	Slow blow 115V	2.5 Amp
<b>Power consumption</b>	Standby	30 VA
	Maximum	100 VA
<b>Heat output</b>	Standby	16 Watt
	Full operation	30 Watt

## Instrument description

### Starrsed Inversa environment:

<b>Sound level</b>	Less than 58 dBA
<b>Environment temperature</b>	18 - 28 °C
<b>Relative humidity</b>	10-90%

### Starrsed Inversa overall dimensions:

<b>Dimensions</b>	Width	330 mm
	Height	770 mm
	Depth	530 mm
	Weight (without fluids)	23 kg

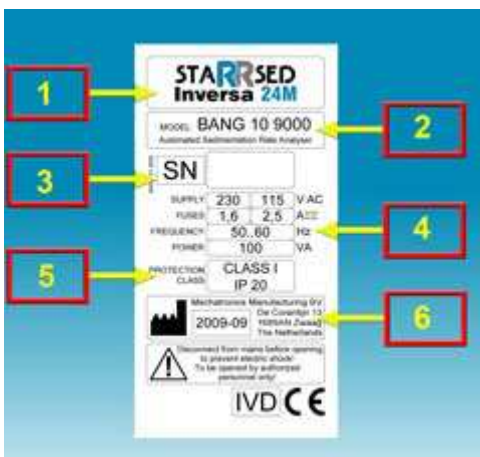
### Starrsed Inversa table size:

<b>Table size (recommended)</b>	Width	600 mm
	Depth	750 mm

## 2.2.1. CE Mark Starrsed Inversa

The CE Mark is found on the Mechatronics instrument identification plate, an illustration of which is shown below with explanations.

The instrument identification plate is fitted at the left side of the rear panel of the Starrsed Inversa.



Explanation:

1. Instrument name Starrsed Inversa
2. Instrument type and model
3. Instrument serial number
4. Electrical information

5. Protection class
6. Manufacturer information and Date of manufacture

## 2.3. Accessories kit

The Starrsed Inversa comes with an accessories kit. For a complete list of the the contents of accessories kit, see **Appendix - Article reference list Inversa** (on page 90)

### 3. GENERAL SAFETY INSTRUCTIONS

The instrument described in this manual is designed to be used by properly trained personnel only. For the correct and safe use of this instrument it is essential that both operating and servicing personnel follow generally accepted safety procedures in addition to the safety precautions specified in this manual.

- Execute your work according to this manual. Read the instructions before operating the instrument. Observe all cautionary markings in the manual and on the instrument. Keep this manual for future reference.
- Follow the bio safety procedures when working with blood-contaminated parts.
- Be cautious to prevent stinging during cleaning or replacing the needle assembly.
- Repair can only be executed by trained and qualified personnel.
- Wear protective clothing.
- When the instrument is running it is not allowed to:
  - Open and remove safety covers.
  - Touch moving parts.
- It is not allowed to give access to the instrument to a non-authorised person at any time.
- Whenever it is likely that safety-protection has been impaired, the instrument must be made inoperative and be secured against any unintended operation. The matter should then be referred to qualified technicians.
- Safety protection is likely to be impaired if, for example, the instrument fails to perform the intended measurements or shows visible damage or unusual smells, smoke, liquids are flowing out.

#### 3.1. Safety warning

When there was an incident with the Starrsed Inversa which caused damage to the instrument, please notify your superior and your local equipment dealer before you continue using the instrument.

**Example:**

- A collision with a moving object or a person
- Something falling on the instrument
- Liquids spilling into the instrument

## 4. INSTALLATION

The instrument must be unpacked, installed and checked by a trained engineer prior to first operation.



Detailed installation instructions are given in the Starrsed Inversa Service manual MRN-145.

## 5. LABELS AND STICKERS

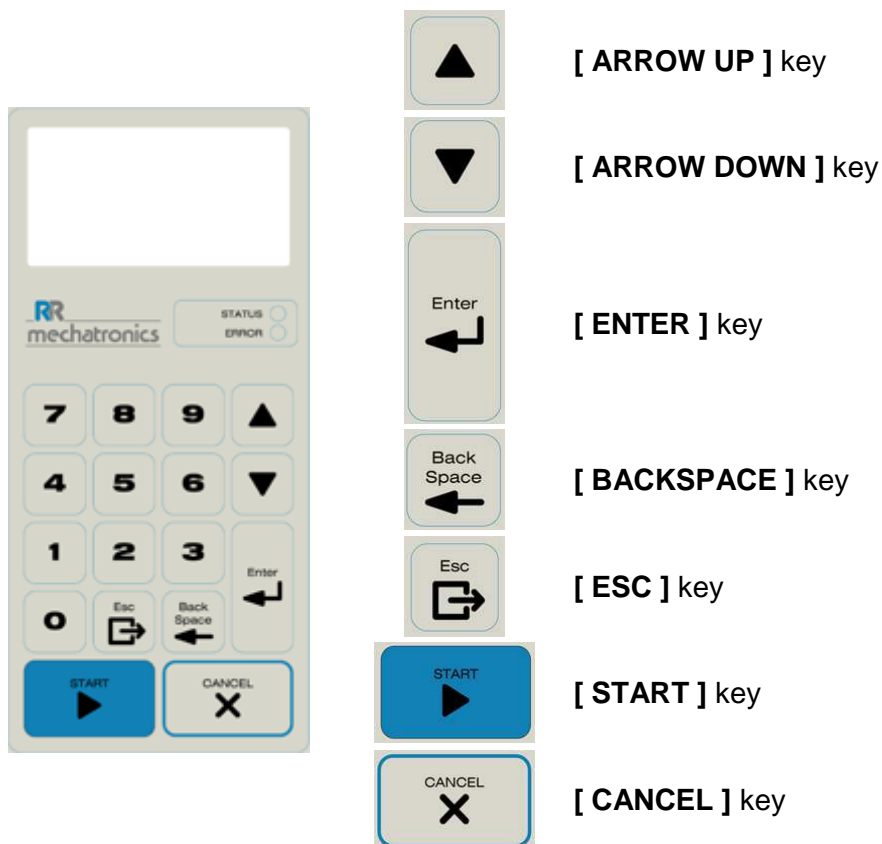
### 5.1. Stickers for the onboard reagents bottles



These stickers are used on the onboard reagent bottles. For more information about these bottles see sections:

- **Waste disposal** (on page 67)
- **Diluent** (on page 57)
- **X-Clean** (on page 57)

## 6. USER INTERFACE



## 6.1. Navigating through the menus

The main menu is displayed after start-up.

The bottom line of the display shows which keys are valid in the context of the selected menu or function.

To **start** functions or access other menus, you can either:

- Press the required row number on the keyboard. The function or menu is activated automatically.
- Scroll to the required row using the arrow keys and press [ **ENTER** ] to activate.

The menus SETTINGS and SERVICE contain **more functions** than can be displayed on one screen.

To access the next screen you can either:

- Press number **7** on the keyboard.
- Scroll to row "7 NEXT" using the arrow keys and press [ **ENTER** ].
- When the cursor is on row "7 NEXT", scroll further down with [ **ARROW DOWN** ].

To **leave** these menus, you can:

- Press [ **ESC** ] to return to the previous screen.
- When the cursor is on the top row ("1"), scroll further up with [ **ARROW UP** ] to return to the previous screen.
- Keep [ **ESC** ] pressed for 2 seconds to return directly to the main menu.

The access depends on the use of the appropriate chip cards.

## 6.2. Start-up screen



The start-up screen is shown for approx. 5 sec. after the Starrsed Inversa is switched on. The software version appears at the bottom of this screen.

### 6.2.1. Start Printout after Switch ON

When a card type A - E or a Q card is present in the card reader of the Starrsed Inversa the following information will be printed after Switch ON.

Example of a print out after switching the Starrsed Inversa ON :

	Column 1	Column 2	Column 3
	<b>StaRRsed Inversa24M</b>		
Line 1	S/N:		123456789ABC
Line 2		30-06-2011	09:00:45
Line 3		Dealer Code:	1234567
Line 4		D-factor:	0
Line 5		Credits:	-
Line 6		Total counts:	12345
Line 7		Serv. count:	1234
Line 8			123456A00087 123456Q00002

In line 8 the serials numbers of the used cards are displayed.

### 6.3. Warning screen Prime

Prime
Last Prime more than 12h ago!
Prime now? (Recommended)

This warning screen appears when the Starrsed Inversa has been idle or switched off for more than 12 hours. Press [ **ENTER** ] to start the function. This will ensure that the fluid lines are correctly filled with diluent. This function can also be started manually at a later time.

## 6.4. Warning screen End of day wash

```

End_of_day wash
Last
End_of_day wash
more than 12h ago!




End_of_day wash now?
(Recommended)
  
```

This warning screen appears when the End-of-day wash was not done after the last sample run and the Starrsed Inversa has been idle or switched off for more than 12 hours. Press [ **ENTER** ] to start the function. This will ensure that the pipettes are cleaned thoroughly. This function can also be started manually at a later time.

## 6.5. Menu structure Main menu Starrsed Inversa

```

1 SAMPLE MODE
2 Patient/pos. data
3 End_of_day wash
4 Prime
5 Settings
6 Service
7 Card & Credits
  
```

 =ESC   
  =SELECT   
 

## 6.6. Menu structure User and Supervisor Overview Starrsed Inversa

**Note:** The User options are shown in this colour

The supervisor options are shown in this his colour.

**Note:** Software version Main 2.04, Slave 1.23, Display 2.19

1 SAMPLE MODE	5 Settings (Contd)
2 Patient/pos. data	
1 Patient data 2 Position data 3 Print data 1 Today's results 2 Yesterday's results 4 Date 6 Cancel print job 4 Print raw data 1 Print data 2 Print graph 5 Send data 1 Today's results 2 Yesterday's results 3 Single result 4 Date 7 Delete data 1 Delete pipet data 2 Delete hist. data	1 Set piston position 2 Set blood sensor 3 - 4 Barcode reader 5 Max.needle current 7 Next  1 Factory settings
3 End_of_day wash	6 Service
4 Prime	
5 Settings	
1 En/disable pipet 2 Print settings 3 Set waste sensor 7 Next 1 30 min. method 2 EDTA mode 3 Temperature 4 Tcorr 5 QC Settings 1 Use assay range 2 Custom NORMAL range 3 Custom ABNORM range 4 QC request to LIMS 5 QC result to LIMS 6 Auto remove link 7 Linked ID's 6 Carousel position 7 Next  1 DST 2 Result at limit 3 Printer (results) 4 Date / Time 5 Language 6 ESR time (min) 7 Next  1 Protocol 2 Baudrate 4 Checksum 5 ACK/NACK 6 30 minute output 7 Next	1 Error history 1 Show error history 2 Print error history 3 Clear error history 2 Software versions 3 Display S/N 4 Bottle alarm OFF 7 Next 1 Motor control 1 Waste M34 2 Meas. M28 3 Nozzle M29 4 Filling M30 5 Needle M31 6 Gripper M32 7 Carousel M33 2 Valve control 1 Noz-Ndl V23 2 Dil-CIn V24 3 Venting V25 4 Blood V26 5 Diluter V27 3 Sensor status 4 Measure pipet 5 Read barcode 6 Replace pipet 7 Next  1 Empty pipet 2 Empty all pipets 3 Empty sample pipets
	7 Card & Credits
	1 Load credits 2 Read service card 3 Print credit status

## 6.7. User menu section

User functionality can be accessed with all types of Chip cards.

### 6.7.1. Main menu

```

1 SAMPLE MODE
2 Patient/pos. data
3 End_of_day wash
4 Prime
5 Settings
6 Service
7 Card & Credits
  
```



=ESC



=SELECT



### 6.7.2. Menu 1 Sample Mode

```

STARSED Inversa 24M
ID:
Ready!

EDTA                                P19
01/09/2014                        22° C
  
```



Sampling

The sample screen shows the current sample ID and status.

### 6.7.3. Menu 2 Patient / pos. data (User)

```

Patient/pos. data
1 Patient data
2 Position data
3 Print data
4 Print raw data
5 Send data
6
7
  
```



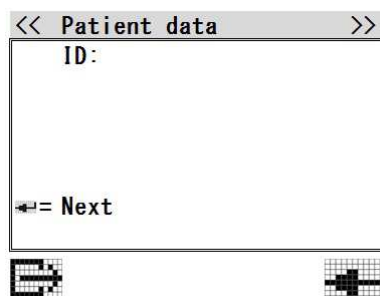
=ESC



=SELECT



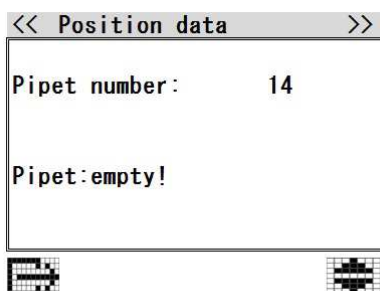
### 6.7.3.1. Menu Patient data



Use this function to check the sample status of a particular patient in the data storage of the Starrsed Inversa.

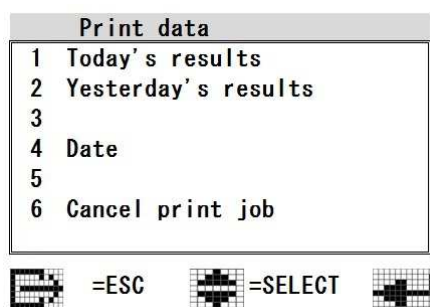
Put the sample tube into the needle holder and press [ **ENTER** ] to get the patient ID from the barcode label or enter the ID manually (only numeric input) and then press [ **ENTER** ].

### 6.7.3.2. Menu Position data



Use this function to check the status of a particular pipette. Use the [ **ARROW UP** ] and [ **ARROW DOWN** ] keys to scroll through the pipettes.

### 6.7.3.3. Menu Print data



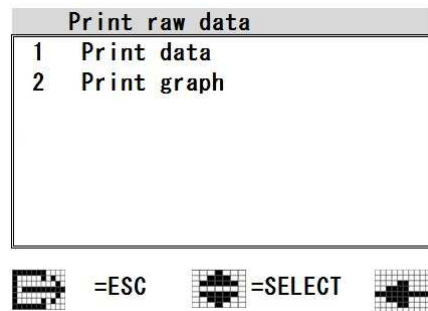
Press [ **ENTER** ] to start the function. Use these functions to print all sample results from the selected day on the build-in printer.

Menu DATE:

Enter the day number and press [ **ENTER** ]. Then continue in the same way with the month and year.

**Note:** When there is no input during 60 seconds the input option is closed.

#### 6.7.3.4. Menu Print raw data



Use these functions to print the raw measurement data of a particular sample. The raw data can be used to analyse a sample in detail in case of unexpected results.

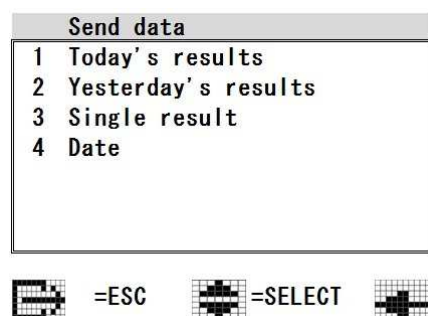
Menu PRINT DATA:

Put the sample tube into the needle holder and press [ **ENTER** ] to get the patient ID from the barcode label or enter the ID manually (only numeric input) and then press [ **ENTER** ].

Menu PRINT GRAPH:

Put the sample tube into the needle holder and press [ **ENTER** ] to get the patient ID from the barcode label or enter the ID manually (only numeric input) and then press [ **ENTER** ].

#### 6.7.3.5. Menu Send data



Menu TODAY'S RESULTS and YESTERDAY'S RESULTS:

Press [ **ENTER** ] to start the function.

Use these functions to send all sample results from the selected day to the HOST.

Menu SINGLE RESULT:

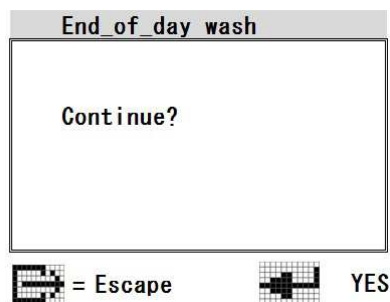
Enter Patient ID, select the required result in case of more than one result with [ **ENTER** ].

To send one result to the HOST press [ **START** ].

Menu DATE:

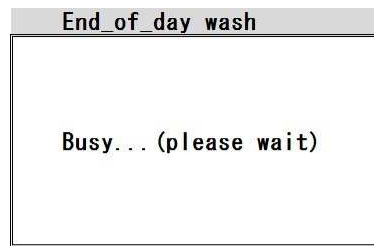
Enter Day-Month-Year and results will be send to the HOST.


#### 6.7.4. Menu 3 End-of-day wash



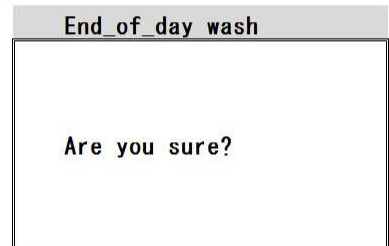
Press [ **ENTER** ] to start the function.

The function may be cancelled by pressing  
[ **CANCEL** ].

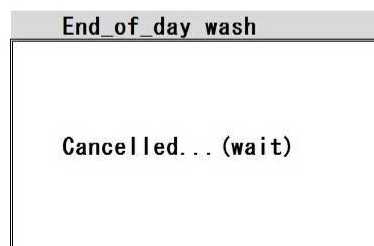



 = Cancel

Press [ **ENTER** ] to continue.



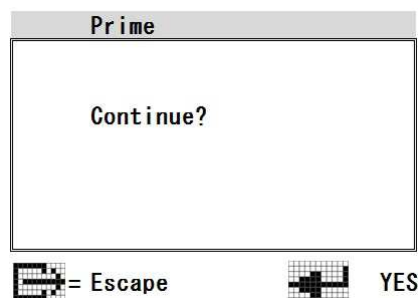
 = Escape  YES



 = Cancel

When the last sample is more than 12 hours ago an END\_OF\_DAY WASH warning is shown on the display with the recommendation to activate the END\_OF\_DAY WASH function.

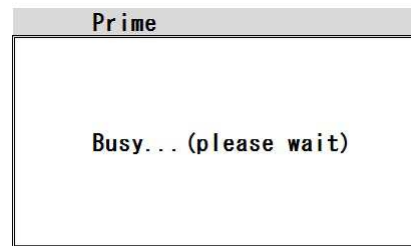
### 6.7.5. Menu 4 Prime




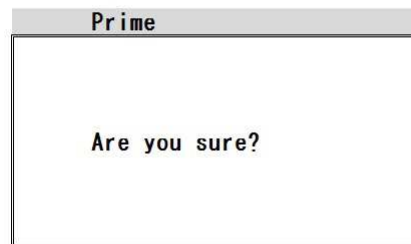
Press [ **ENTER** ] to start the function.


The function may be cancelled by pressing **[ CANCEL ]**.

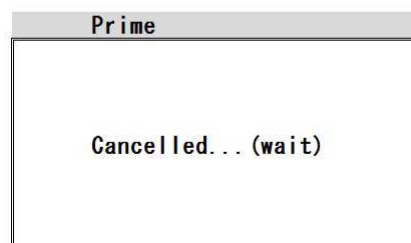
Press **[ENTER]** to continue.




 = Cancel



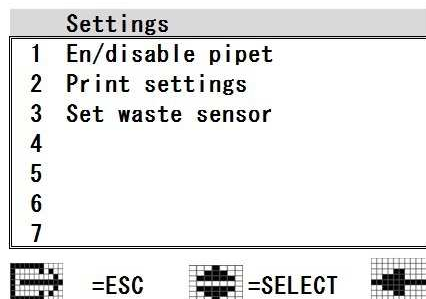
 = Escape  YES



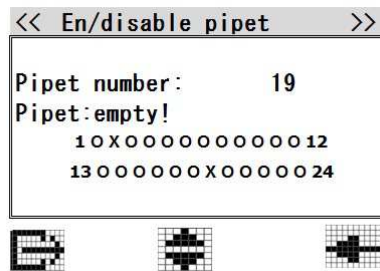
 = Cancel

When the last prime function is more then 12 hours ago a PRIME warning is shown on the display with the recommendation to activate the PRIME function.

### 6.7.6. Menu 5 Settings (User)



### 6.7.6.1. Menu En/disable pipet



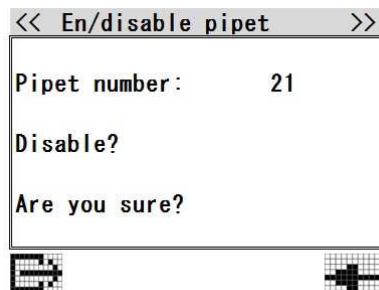
The status of the current pipette is shown at the top.

The lower part shows a representation of all pipettes in the carousel counted from left to right and from top to bottom. Enabled pipettes are marked with a dot (O), disabled pipettes are marked with a cross (X).

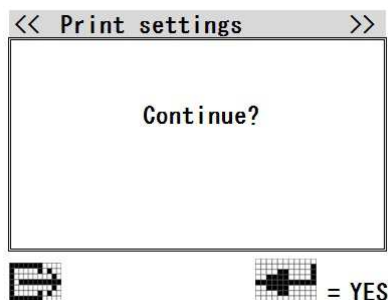
The Starrsed Inversa checks automatically for leaking pipettes by comparing the column height measured directly after the aspiration with the column height obtained during the final measurement. Leaking pipettes are automatically disabled for future use and must be enabled manually.

**Note:** In this example, pipettes 2 and 18 are disabled.

Use the [ **ARROW DOWN** ] or [ **ARROW UP** ] keys and select the required pipette number, then press the [ **ENTER** ] key to toggle the setting to the opposite of the current state.

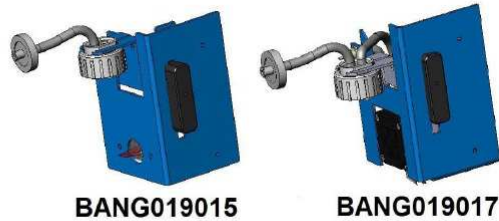
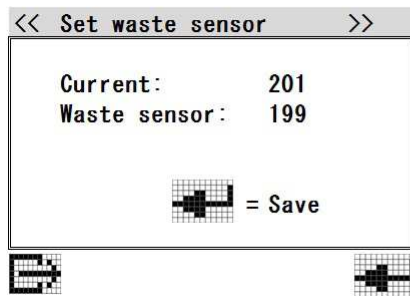


### 6.7.6.2. Menu Print settings



Press [ **ENTER** ] to start the function. The instrument settings are printed on the build-in printer.

### 6.7.6.3. Menu Set waste sensor



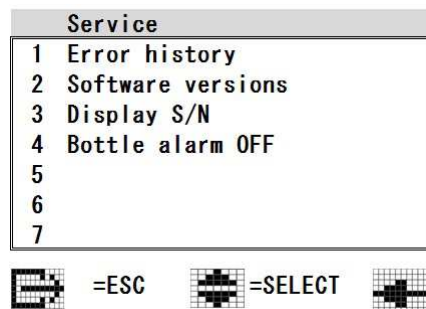
CURRENT = current setting

WASTE SENSOR = actual measured value

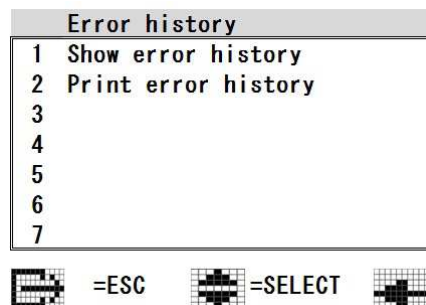
BANG019015: In case of a new waste bottle: If the values do not match, press [ **ENTER** ] to save the new setting. Value range 130-240.

BANG019017: Value set during installation (Value range 190-210).

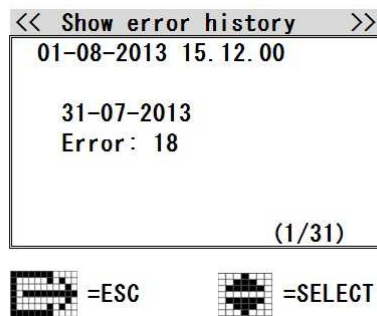
### 6.7.7. Menu 6 Service (User)



#### 6.7.7.1. Menu Error history



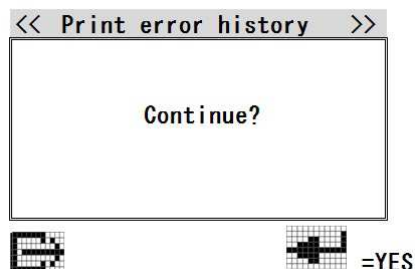
Menu SHOW ERROR HISTORY:



The first row shows the current date and time. The third row shows the date and time when the displayed error occurred.

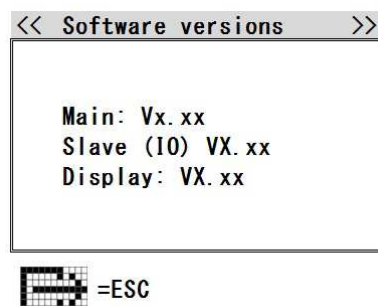
Use the [ **ARROW DOWN** ] or [ **ARROW UP** ] keys and select the next error code.

Menu PRINT ERROR HISTORY

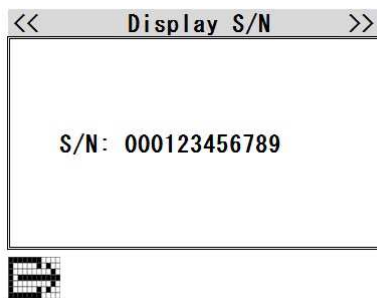


Press [ **ENTER** ] to start the function. The error history is printed on the build-in printer.

#### 6.7.7.2. Menu Software versions



### 6.7.7.3. Menu Display S/N



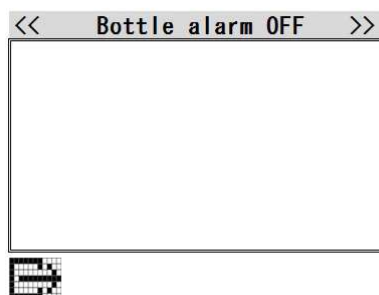
The displayed number is the instrument security number which is a security feature associated with the chip card system.



#### NOTE:

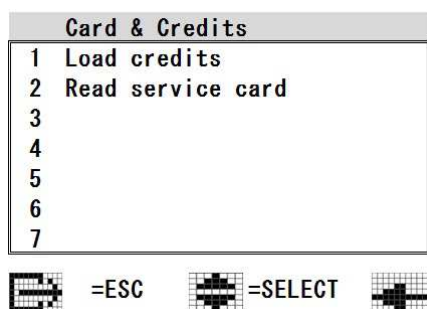
This **security number** is *not* the same as the **serial number** of the instrument. The serial number is shown on the instrument type label on the back of the Starrsed Inversa.

### 6.7.7.4. Menu Bottle alarm OFF



Use this function to temporarily turn off the buzzer during a bottle alarm (e.g. diluent bottle empty or waste bottle full).

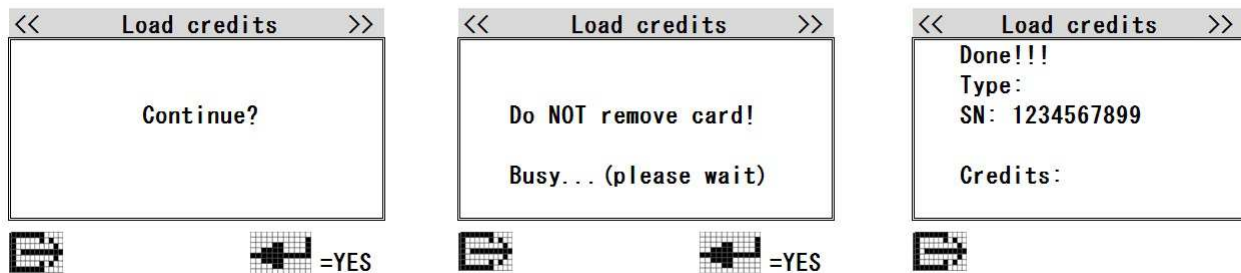
### 6.7.8. Menu 7 Card & Credits (User)



Select 1 LOAD CREDITS credits, continue and press [ **ENTER** ] to start the function.  
This function is used to load credit units from a credit chip card into the internal memory of the Starrsed Inversa.

Select 2 READ SERVICE CARD, continue and press [ **ENTER** ] to start the function.  
This function is used to unlock the protected menus and functions.

#### 6.7.8.1. Menu Load credits



When credits are stored in the Starrsed Inversa the new information is shown.

This is the total amount of available credit units in memory

TYPE: This is the code letter for the type of chip card

SN: This is the serial number of the chip card

#### 6.7.8.2. Menu Read service card



After reading a service card the following information is shown.

TYPE: This is the code letter for the type of chip card

SN: This is the serial number of the chip card

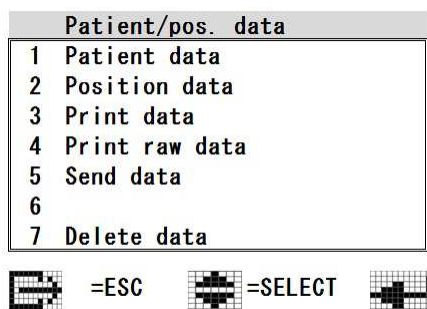
Enter the required password for the inserted type of service chip card and press [ **ENTER** ]. Wait until the display shows "CARD OK !".

## 6.8. Lab Supervisor menu section

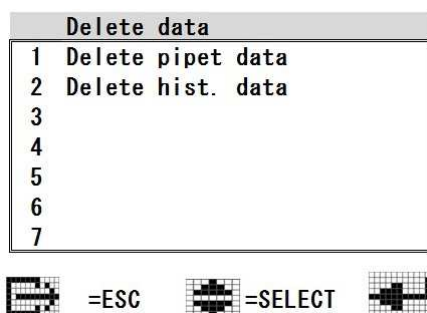
**Lab Supervisor** functionality can be accessed with chip card type **S**.

Only the additional supervisor functions and submenus are explained in this section. For the standard user menu refer to the "**User menu section** (on page 27)".

### 6.8.1. Menu 2 Patient / pos. data



#### 6.8.1.1. Menu Delete data



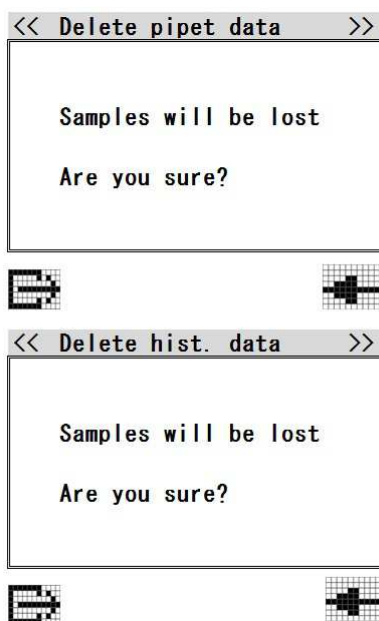
Function 1 DELETE PIPET DATA is used to delete all data of samples currently in the pipettes. These samples have not been measured yet

Function 2 DELETE HIST. DATA is used to delete all stored data (results) of previously measured samples.



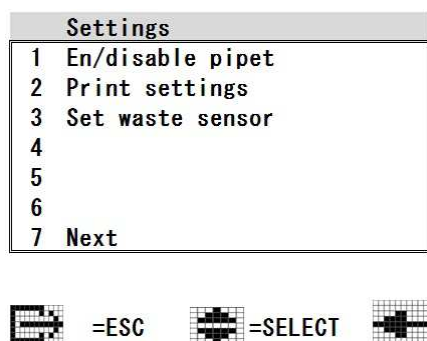
#### **Warning:**

Using these functions will erase all of the selected data from the memory of the Starrsed Inversa. Once erased, the data can not be recovered!

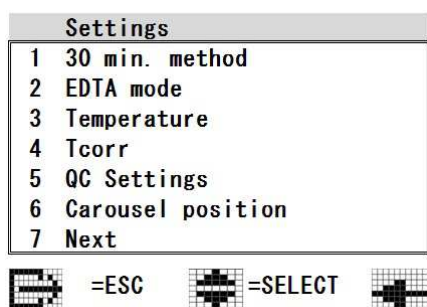


Press [ **ENTER** ] to confirm the selection and start the function.

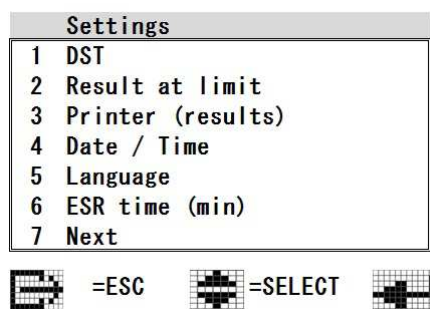
### 6.8.2. Menu 5 Settings (Supervisor)



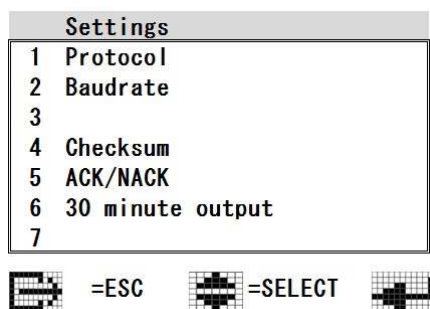
Next submenu:



Next submenu:



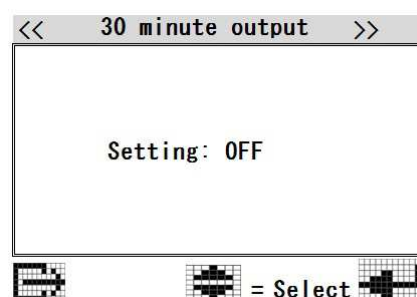
Next submenu:



To return to the previous settings screen, press [ **ESC** ].

To return directly to the Main menu, keep [ **ESC** ] pressed until the Main menu is displayed.

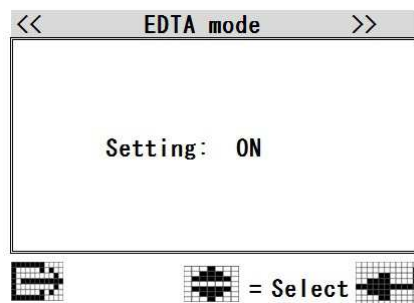
#### 6.8.2.1. Menu 30 min. method



When this setting is ON, the pipettes are measured after 30 minutes instead of 60 minutes. The obtained reading is converted to a predicted 60 minute result.

Use the [ **ARROW DOWN** ] or [ **ARROW UP** ] keys and select the required option.  
Then press [ **ENTER** ] to save the new setting.

### 6.8.2.2. Menu EDTA mode



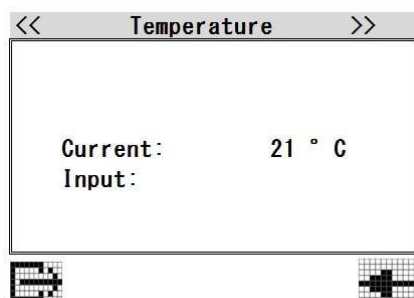
Use the [ **ARROW DOWN** ] or [ **ARROW UP** ] keys and select the required option. Then press [ **ENTER** ] to save the new setting.



**NOTE:**

A small hardware modification is necessary to switch between EDTA mode and Citrate mode. See work instruction **WI-405** (on page 124) for details.

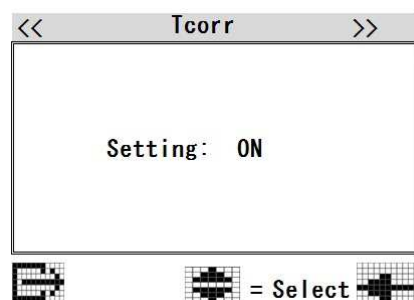
### 6.8.2.3. Menu Temperature



The displayed value is the temperature according the build-in thermometer of the Starrsed Inversa.

1. Check the room temperature near the pipettes with a room thermometer.
2. Enter the measured temperature from the room thermometer as the current value for the temperature sensor.
3. Then press [ **ENTER** ] to save the new setting.

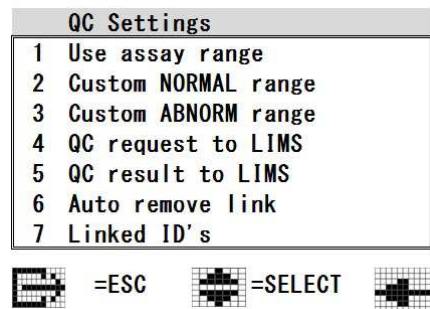
### 6.8.2.4. Menu Tcorr



This option is used to set if Temperature correction is to be applied on the measured ESR results.

Use the [ **ARROW DOWN** ] or [ **ARROW UP** ] keys and select the required option.  
Then press [ **ENTER** ] to save the new setting.

#### 6.8.2.5. QC Settings



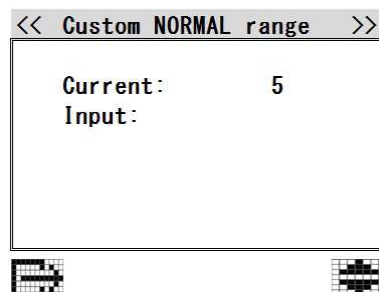
In "QC settings" the following options can be selected:

##### 1. USE ASSAY RANGE

- The default assay range which is predetermined for the current batch of Starrsed Control is used. These ranges cannot be changed in this option. (=Default setting)

##### 2. CUSTOM NORMAL RANGE

- The lab can establish their own acceptable range for Starrsed Control NORMAL range, can be set from a minimum of +/- 2 mm to a maximum of +/- 15 mm. Numbers outside this range cannot be saved.



##### 3. CUSTOM ABNORM RANGE

- The lab can establish their own acceptable range for Starrsed Control ABNORMAL range, can be set from a minimum of +/- 2 mm to a maximum of +/- 15 mm. Numbers outside this range cannot be saved.

Note: It is advised to use the default assay ranges. Use caution when setting the custom ranges. A too narrow range may cause unjustified rejection of QC sample results, subsequent rejection of patient results and undue burden on maintenance.

---

#### 4. QC REQUEST TO LIMS

- **ON:** A sample request for the QC sample is send to LIMS. The QC sample will only be processed if the LIMS responds with YES.  
Use this setting if the ESR result of the QC sample will be send to LIMS as well and LIMS requires that all samples are requested first.  
If the QC sample is linked with a Lab ID, the sample will be requested at LIMS with the Lab ID.  
If the QC sample is used with the original Starrsed Control sample ID, the sample will be requested at LIMS with the Starrsed Control sample ID.
- **OFF (=Default setting):** All QC samples will be processed without requesting at LIMS.

#### 5. QC RESULT TO LIMS

- **ON:** QC results are send to the LIMS as a standard ESR result.  
If the QC sample is linked with a Lab ID, the result will be send to LIMS with the Lab ID.  
If the QC sample is used with the original Starrsed Control sample ID, the result will be send to LIMS with the Starrsed Control sample ID.

---

Note: When the MECHATRONICS-01 or MECHATRONICS-02 protocols are used, the "Sample code" (or "Sample type") flag is set accordingly to mark the QC samples.

---

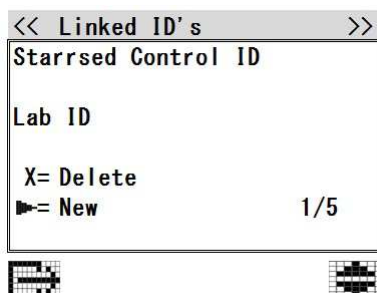
- **OFF (=Default setting):** Results will not be send to LIMS, data is only available on the Starrsed Inversa.

#### 6. AUTO REMOVE LINK

- **ON (=Default setting):** The link between Starrsed Control Sample ID and Lab ID will be deleted after a useable result has been reported for this particular lab ID. For each QC sample a new link must be created. This link will stay active if there is no result or a general ESR error is generated. This setting is useful when the lab issues a new and unique Lab ID for every QC sample.
- **OFF:** The link will be available until its deleted manually. This could be useful when using a general Lab ID for QC monitoring. Only in case of a new batch of Starrsed Control a new link has to be created.

## 7. LINKED ID'S

A maximum of five linked ID's can be maintained. To enter a new link, scroll to an empty position or press New.



If the Lab ID is numeric:

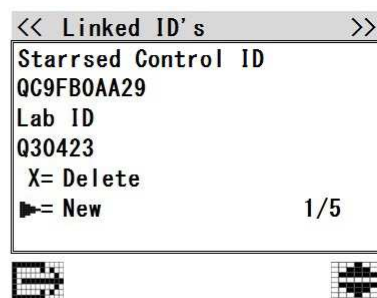
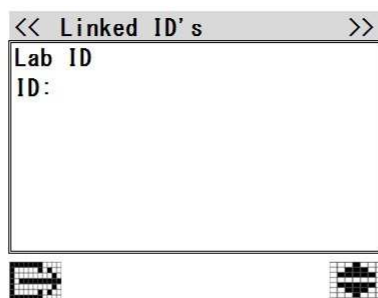
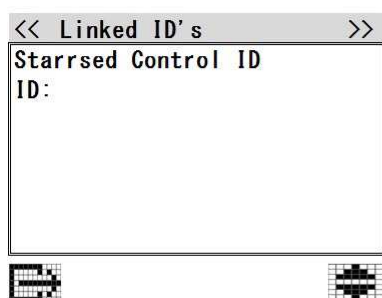
1. Place the Starrsed Control tube on sample position, press Enter to scan the barcode.
2. Enter the Lab ID, press Enter to confirm.

The link-information is showed on the screen, the link is activated.

If the Lab ID is alphanumeric:

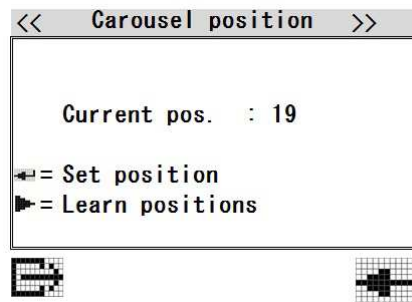
1. Use a sample tube with the correct Lab ID-label (only numeric values can be entered manually).
2. Place the Starrsed Control tube on sample position, press Enter to scan the barcode.
3. Place the tube with Lab ID on sample position, press Enter to scan the barcode.

The link-information is showed on the screen, the link is activated.



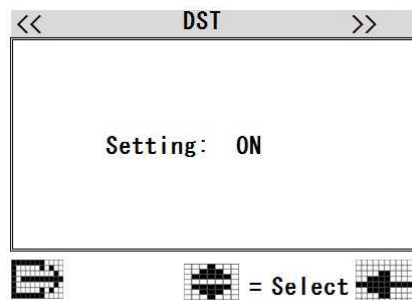
If five links are filled in, the first one will be replaced when a new link is added. A Lab ID which is already used cannot be saved.

#### 6.8.2.6. Menu Carousel position



These functions are used to reset the correct pipette positions that are stored in memory. The displayed value is the pipette number that should currently be present at the nozzle position. Press the [ **ENTER** ] or [ **START** ] key to show the Input option. Enter the pipette number which is actually present at the nozzle position and press [ **ENTER** ] to activate the action.

#### 6.8.2.7. Menu DST



This function is used to switch the internal clock to **Daylight Saving Time** (also called *Summertime*).

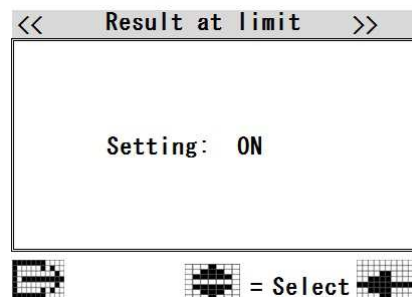
Use the [ **ARROW DOWN** ] or [ **ARROW UP** ] keys and select the required option. Then press [ **ENTER** ] to save the new setting.

---

**Note:** Can only be set between 03:00 and 21:00 and when the carousel is empty.

---

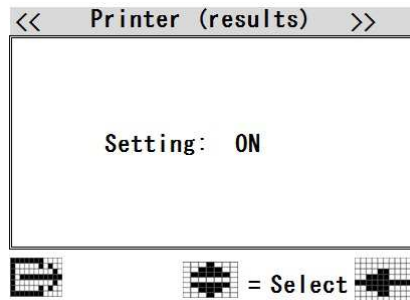
#### 6.8.2.8. Menu Result at limit



See section "**Results at limit errors** (on page 75)" for details of this option.

Use the [ **ARROW DOWN** ] or [ **ARROW UP** ] keys and select the required option.  
Then press [ **ENTER** ] to save the new setting.

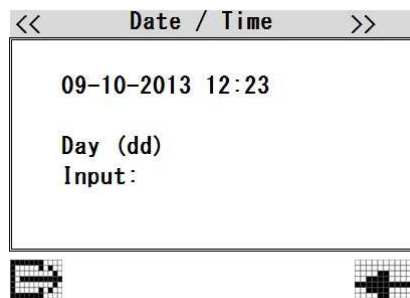
#### 6.8.2.9. Menu Printer (results)



This function is used to switch if ESR results must be printed on the build-in printer. Printing may not be necessary if all results are send to a HOST.

Use the [ **ARROW DOWN** ] or [ **ARROW UP** ] keys and select the required option.  
Then press [ **ENTER** ] to save the new setting.

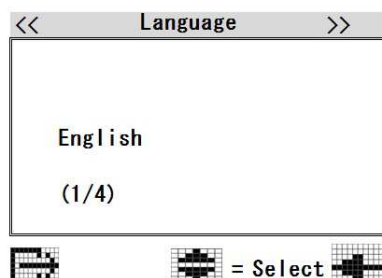
#### 6.8.2.10. Menu Date / Time



To set the system date and time, enter the day number and press [ **ENTER** ]. Then continue in the same way with the month, year, hour and minutes.

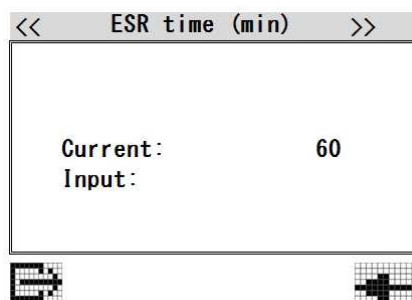
**Note:** When there is no input during 60 seconds the input option is closed.

#### 6.8.2.11. Menu Language



Select the required language for the user interface. A limited number of languages is available.

### 6.8.2.12.Menu ESR time (min)



This function can be used to temporarily set a different sedimentation time for service or maintenance reasons.

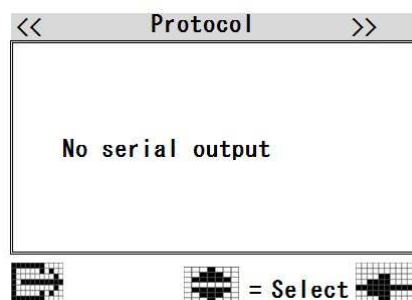
Enter the required sedimentation time. Then press [ **ENTER** ] to save the new setting.



#### NOTE:

This setting is only active as long as the service chip card is present in the card reader. When the chip card is removed, the setting is automatically reset to 30 or 60 minutes according the selected method.

### 6.8.2.13.Menu Protocol



A protocol is a set of rules governing the communication and the transfer of data between machines, as in a computer system. It is also a formal set of rules and procedures to be followed during a request for information before data is transferred between machines and computer systems.

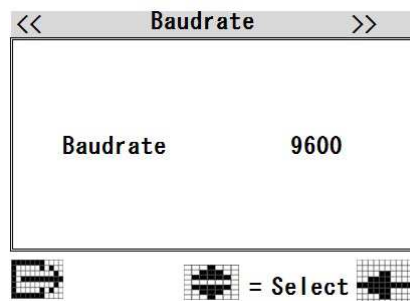
The following protocols can be selected for data transfer to the Laboratory data processor computer.

1. No Serial output
2. MECHATRONICS-01 bidirectional
3. MECHATRONICS-02 unidirectional
4. Compact bidirectional
5. Compact unidirectional
6. Protocol Sysmex R-3500
7. Protocol Sysmex R-3500 unidirectional

The protocol can be set in menu SETTINGS - PROTOCOL. After selecting a protocol, save the new settings by pressing the [ **ENTER** ] key.

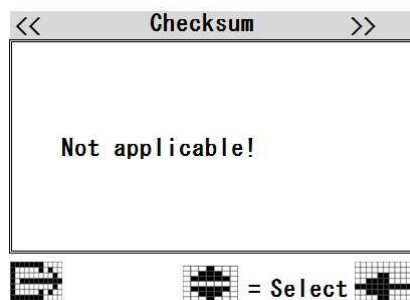
	CHECKSUM	ACK/NACK	30 MINUTE OUTPUT
<b>Serial 2</b>	Not selectable	Not selectable	Not selectable
<b>Serial 3</b>	Not selectable	Selectable	Not selectable
<b>Serial 4</b>	Selectable	Not selectable	Selectable
<b>Serial 5</b>	Selectable	Selectable	Selectable

#### 6.8.2.14.Menu Baudrate



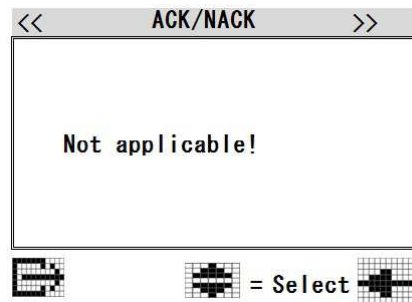
Use the [ **ARROW DOWN** ] or [ **ARROW UP** ] keys and select the required Baud rate ( 2400, 4800, 9600, 19200, 38400 (8-N-1). Then press [ **ENTER** ] to save the new setting.

#### 6.8.2.15.Menu Checksum



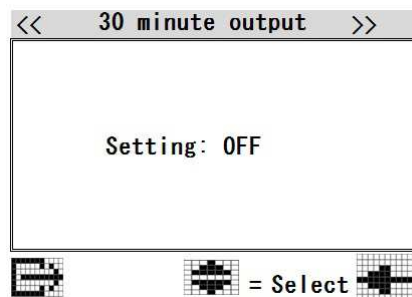
**Note:** This setting is only applicable if the output protocol is set to Compact unidirectional or Compact bidirectional. See **Menu Protocol** (on page 47)

#### 6.8.2.16.Menu ACK/NACK



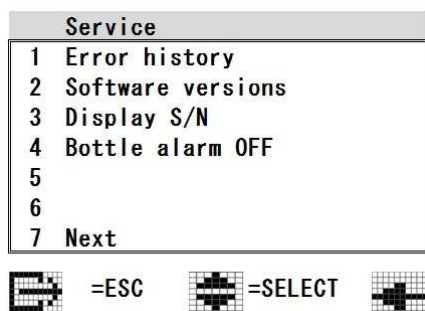
**Note:** This setting is only applicable if the output protocol is set to MECHATRONICS-02 unidirectional or Compact unidirectional. See **Menu Protocol** (on page 47).

#### 6.8.2.17.Menu 30 minute output






**Note:** This setting is only applicable if the output protocol is set to Compact unidirectional or Compact bidirectional.

### 6.8.3. Menu 6 Service (Lab Supervisor)






Next submenu:

Service	
1	Motor control
2	Valve control
3	Sensor status
4	Measure pipet
5	Read barcode
6	Replace pipet
7	Next

 =ESC   
 =SELECT   





Next submenu:

Service	
1	Empty pipet
2	Empty all pipets
3	Empty sample pipets
4	
5	
6	
7	

 =ESC   
 =SELECT   


### 6.8.3.1. Menu Motor control

Service		
1	Waste	M34
2	Meas.	M28
3	Nozzle	M29
4	Filling	M30
5	Needle	M31
6	Gripper	M32
7	Carousel	M33

 =ESC   
 =SELECT   


These functions can be used to test the function of the motors or to move the associated unit to a particular position for service and maintenance reasons.

Select the required motor and use the [ **ARROW DOWN** ] or [ **ARROW UP** ] keys to switch the motor ON or OFF.






#### Warning:

These functions should only be used when there are no samples present that need to be processed.

Use these functions only if sufficient understanding of and experience with the instrument have been gained!

### 6.8.3.2. Menu Valve control

Service		
1	Noz-Ndl	V23
2	Dil-Cln	V24
3	Venting	V25
4	Blood	V26
5	Diluter	V27

 =ESC
  =SELECT
 

These functions can be used to test the function of the valves for service and maintenance reasons.

Select the required valve and use the [ **ARROW DOWN** ] or [ **ARROW UP** ] keys to switch the valve ON or OFF.





**Warning:**

These functions should only be used when there are no samples present that need to be processed.

Use these functions only if sufficient understanding of and experience with the instrument have been gained!

### 6.8.3.3. Menu Sensor status

<< Sensor status >>	
Blood detec. :	126
Meas. head:	40
Temperature:	20°
Pos. sensor :	235
Waste sensor:	200

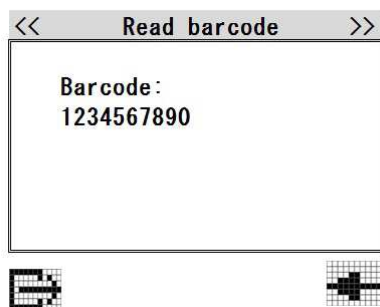



**Note:** Waste sensor: Value range 130-240.

### 6.8.3.4. Menu Measure pipette

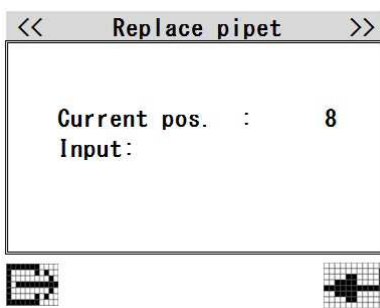
Press the [ **ENTER** ] key to measure the pipette that is currently in front of the measure unit. The result is printed as graph on the build-in printer.

#### 6.8.3.5. Menu Read barcode



To check the function of the barcode reader, place a sample tube with barcode in the needle unit and press the [ **ENTER** ] key. The detected barcode is displayed on the screen (in this example: 1234567890).

#### 6.8.3.6. Menu Replace pipette



This function can be used to move a particular pipette to the door opening when the pipette needs to be replaced.

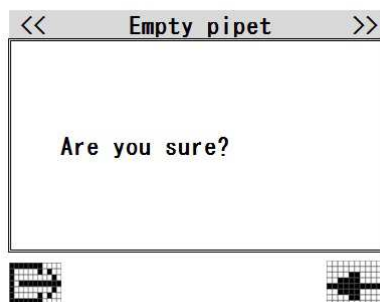
Enter the number of the pipette and press [ **ENTER** ].

#### 6.8.3.7. Menu Empty pipette

This function can be used to empty a pipette that may have remained filled due to an error condition.

The function is performed on the pipette that is currently at the nozzle position.

Press [ **ENTER** ] to confirm the selection and start the function.



Press [ **ENTER** ] to continue.

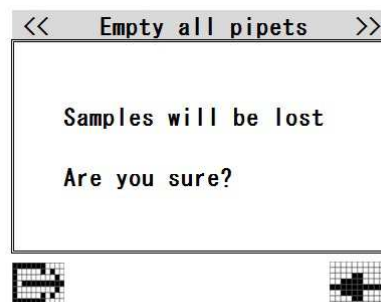


**NOTE:**

To empty another pipette, use function CAROUSEL M33 in the menu MOTOR CONTROL to move the pipette to the nozzle position and then use function EMPTY PIPET.

#### 6.8.3.8. Menu Empty all pipets

This function can be used to empty all pipettes due to an error condition.  
Press [ **ENTER** ] to confirm the selection and start the function.



Press [ **ENTER** ] to continue.

#### 6.8.3.9. Menu Empty sample pipets

This function can be used to empty all filled pipettes due to an error condition.  
Press [ **ENTER** ] to confirm the selection and start the function.



Press [ **ENTER** ] to continue.

## 7. QUICK START-UP

This section describes a quick start-up procedure and a general description of what to do before starting a large batch of samples to run through the system.

### 7.1. Power up sequence

Switch ON procedure:

- Switch the Starrsed Inversa ON.
- Wait until the Main menu is visible on the display.
- The instrument is now ready.

### 7.2. Check list

The laboratory supervisor should check the following instrument settings and select the required options:

- Menu SETTINGS - 30 MIN. METHOD (Default is OFF)
- Menu SETTINGS - EDTA MODE (Default is ON)
- Menu SETTINGS - TCCORR (temperature correction) (Default is ON)



**NOTE:**

A small hardware modification is necessary to switch between EDTA mode and Citrate mode. See work instruction **WI-405** (on page 124) for details.

Check the following things before each large batch of samples:

1. Ensure that a chip card is present in the card reader. This may be any type of chip card.
2. Open the printer and check if enough paper is available. Replace if necessary.
3. Empty the waste container.
4. Check the liquid levels and refill the containers if necessary.

### 7.3. Printer paper replacement

When a red line appears across the length of the printout, the printer paper roll is approaching its end. The remaining paper is sufficient for ca. 24 printed reports. The red line marker is getting more intense as it comes closer to the end of the paper roll.

To open the printer, pull the handle at the top of the flap:



Insert a new paper roll as shown:




## 7.4. Liquid levels and reagents preparation

The liquid levels on the Starrsed Inversa are automatically checked by sensors. To avoid level sensor alarms during routine operation, the liquid levels in the containers should also be checked visually every day.

**NOTE:**

Refill reagent as soon as possible when the level sensor alarm appears.

The audio alarm can be disabled with  SERVICE \ BOTTLE ALARM OFF\, stay in this menu option during refilling the bottle(s).

1. Reagents preparation.
  - Use only the reagent containers which are supplied with the Starrsed Inversa.
  - To open the bulk reagent packages, remove the perforated flap from the cardboard box, pull the opening out of the box and fit the taps.
2. Fill up the containers with the reagents.
3. To remove the containers from the instrument, first pull the slider all the way up, then remove the bottle:



### 7.4.1. Diluent QRR 010931

Sodium citrate diluent is used for the dilution of undiluted EDTA samples and for the automatic rinsing of the sample system between samples.

- Approximately 5 ml Diluent is used for each sample cycle.

The on-board container for Diluent is a 1 liter plastic bottle. Fill the container with Diluent from the 5-liter bulk container (QRR 010931).

The solution should be discarded if it becomes turbid.

If the Diluent does become turbid, clean the Diluent container thoroughly with a 5% Na-hypochlorite solution. After cleaning, rinse the container thoroughly with de-ionized water. Before refilling, flush the Diluent bottle with a little Diluent from the bulk container.



**NOTE:**

The latest version of the Material Safety Data Sheet (MSDS) of the used reagents can be found on our web site [www.rrmechatronics.com](http://www.rrmechatronics.com).

### 7.4.2. X-Clean QRR 010946

X-Clean is a ready-to-use cleaning solution that is used for the End-of-day wash. The solution removes residual proteins from the inner wall of the Westergren pipettes.

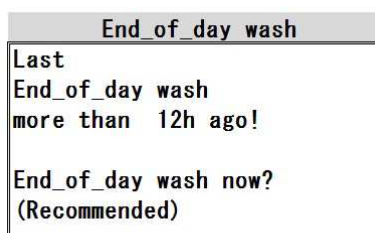
The on-board container for X-Clean is a 1 liter plastic bottle. Fill the container with X-Clean from the 5-liter bulk container (QRR 010946).



**NOTE:**

The latest version of the Material Safety Data Sheet (MSDS) of the used reagents can be found on our web site [www.rrmechatronics.com](http://www.rrmechatronics.com).

## 7.5. Warning screen End of day wash



This warning screen appears when the End-of-day wash was not done after the last sample run and the Starrsed Inversa has been idle or switched off for more than 12 hours. Press [ **ENTER** ] to start the function. This will ensure that the pipettes are cleaned thoroughly. This function can also be started manually at a later time.

## 7.6. Priming the fluid system

After starting the Starrsed Inversa, a warning may appear on the screen stating that the last prime cycle was more than 12 hours ago. Press [ **ENTER** ] to start the priming cycle.

To start the priming manually, go to the Main menu and use the function PRIME. The priming cycle takes ca. 2 minutes to complete.

## 8. SAMPLE ROUTINE PROCEDURE

This section explains the necessary procedures for preparation and processing of blood samples on the Starrsed Inversa.

### 8.1. Sample Mixing

To ensure that the blood cells are evenly dispersed throughout the sample, the sample tube must be mixed immediately before placing it in the sampling unit.

This can be done either manually or by using a sample tube mixer that inverts the tubes. The sample tube must be fully inverted at least 8 times. Do not shake the sample.



NOTE: Ensure that the sample tube contains at least 2 ml of whole blood.

### 8.2. Placing sample tubes on the needle system

After mixing, insert the sample tube into the needle assembly with the cap downwards and the barcode label pointing towards the instrument.



#### 8.2.1. Sample tubes with barcode

1. Start the SAMPLE MODE.
2. Push the [ **START** ] key.
3. Check that the scanned ID number appears on the display.
4. If the ID number does not appear on the display, the barcode could not be read:

1. Rotate the sample tube a little bit and push the [ **START** ] key again.  
or:
2. Enter the ID manually as described in the next section.

**NOTE:**

The sampling may not start immediately if a clean pipette is not yet available, but will start automatically when a clean pipette is available within 90 sec.

To prevent the aspiration of a not properly mixed sample, sampling will not start automatically when it takes longer than 90 sec. for a pipette to become available.

The operator must then remix the sample and push the [ **START** ] key again.

---

### 8.2.2. Sample tubes without barcode

If the sample tube has no barcode or the barcode can not be read, you can enter the sample ID manually.

1. Start the SAMPLE MODE.
2. Enter the ID number.
3. Push the [ **START** ] key.

**NOTE:**

The sampling may not start immediately if a clean pipette is not yet available, but will start automatically when a clean pipette is available within 90 sec.

To prevent the aspiration of a not properly mixed sample, sampling will not start automatically when it takes longer than 90 sec. for a pipette to become available.

The operator must then remix the sample and push the [ **START** ] key again.

---

### 8.3. Aspirating the sample

When a clean pipette is available, the needle assembly goes down and pushes the sample tube over the needles. The necessary blood volume is drawn from the sample tube into a tube (T3) until the blood sensor is triggered.

When the blood sensor is triggered, the piston of the Westergren pipette is pulled up to aspirate the sample into the pipette. During this fill motion the diluter syringe is driving the diluent via the nozzle into the blood stream.

**NOTE:**

If the Starrsed Inversa is set to bidirectional communication with a HOST and ESR measurement is not required for this sample, the message "No ESR!" is shown on the display. The sample will not be aspirated and may be removed from the needle unit.

---

## 8.4. Aborting the sample sequence

If a clean pipette is not available yet and sampling has not started yet, it is possible to abort the sample by pressing the [ **CANCEL** ] key.



---

**NOTE:**

As soon as the tube starts to move over the needle, it is not possible to cancel the aspiration sequence.

---

## 8.5. Automatic rinsing of the sample system

After each aspiration, the sample needle, sample tubes and fill nozzle are automatically washed with diluent.

## 8.6. Fill errors during sampling

After filling the sample into the pipette, the quality of the aspiration is checked by pre-measuring the pipette. The following parameters are checked:

- the column height
- the usage of diluent
- possible air bubbles

In case of air detection at the bottom of the pipette E20 FILL ERROR! is shown on the display. This error indicates dilution problems or insufficient sample flow.

If there are other deviations, a beep will sound after the check and an ESR Error or warning is reported.

## 9. QUALITY CONTROL

### 9.1. Monitoring measurement quality with Starrsed Control

Starrsed Control is an in-vitro diagnostic quality control material to monitor the accuracy and precision of Erythrocyte Sedimentation Rate (ESR) instruments and procedures. This instruction is only applicable for Starrsed Control, used on Mechatronics ESR Starrsed instruments.

Starrsed Control is available in:

- Abnormal range (Level A)
- Normal range (Level N)

### 9.2. Limitations

Starrsed Control is to be used for Erythrocyte Sedimentation Rate testing only and shall not be used to control any other hematology procedure.

Starrsed Control shall not be used as a standard.

Starrsed Control should not be used past the expiry date.

Mechatronics as supplier of the Starrsed Control shall not be liable for any claimed damages arising from other than intended usage.

### 9.3. Expected value range

Starrsed Control is assayed for the Starrsed ESR analyzers.

The assayed mean values and expected ranges are derived from multiple analyses at different sites and on multiple instruments. The values, provided on the package insert and encoded in the tubes barcode, are specific for this lot of product. The lab should establish its own acceptable ranges. Whenever the Controls fail to perform consistently within the acceptable ranges, patient results should be considered invalid. Contact your Starrsed instrument provider for assistance. If results vary outside the specified assay ranges, discard the tube and utilize a new tube. If difficulties persist, contact your supplier for further assistance and/or instructions.

### 9.4. Temperature correction

The assayed values are based on an 60 minutes ESR, with dilution and temperature correction. Therefore, the measured ESR value should be compared with the expected value *using temperature correction*. The calculation of a 30 minute measurement to a 60 minute ESR result with temperature correction influences the QC result.

See chapter **QC Results** (on page 64) for more information.

## 9.5. Quality control procedure

Starrsed Control is provided in ready-to-use sample tubes and is used in the same manner as patient samples. Starrsed Control is to be used for the Westergren method with dilution only as prescribed by the "ICSH review of the measurement of the ESR" (2011) and the "CLSI Procedures for the ESR Test; Approved standard; H02-A5" (2011).

*Citrate mode:* When the Starrsed analyzer is used in the Citrate mode, the Starrsed Control material must be diluted manually by transferring the necessary amount of material into a pre-citrated ESR blood collection tube. Immediately after re-suspending, transfer the necessary amount of material into a pre-citrated tube according instructions of the tube manufacturer. Close the tube with the mixture and invert at least 12 times, then place the sample into the analyzer.

1. *When using LAB ID:* Link the Lab ID with Starrsed Control Sample ID, attach the lab ID label on the tube on top of the original Starrsed Control label.
2. Invert the Starrsed Control tube until packed cells have been completely re-suspended. Continue mixing for 30 seconds (at least 12 complete inversions). Avoid foaming. DO NOT VORTEX.  
**NOTE:** To ensure consistent and reproducible results, the Control material must be thoroughly mixed and handled in the same manner each time.
3. Place Starrsed Control tube immediately after mixing into the analyzer.
4. Start the Sample mode. The Starrsed Control sample is processed in the same manner as a patient sample. Depending on the settings in "QC settings", a request and/or result is send to the LIMS.
5. Restore tube after each use (at 18°-30°C).

For detailed information see the Starrsed Control Package Insert.

The contents of one tube of 5ml is sufficient for three Control samples. Do not mix residual material with material from other tubes. Do not re-use empty tubes.

See chapter QC Error messages for handling QC errors.

If the QC sample is out of range the message "CONTROL OUT OF RANGE!" appears. This warning is also given when patient sampling is started. Press ESC for aborting patient sampling, press ENTER to continue sampling. It depends on the general QC procedure of the Lab if it is allowed to perform patient samples after the warning "CONTROL OUT OF RANGE!".



---

Starred Control should be disposed of as medical waste.

---

## 9.6. QC Results

The measured QC results are compared with the Assay mean value and the acceptable range. The applicable values for the acceptable range depend on the user setting. See chapter "**QC Settings** (on page 42)" for more information.

If applicable, the QC result is reported to LIMS using the chosen settings regarding temperature correction, display of dilution rate and limit error settings.

### 9.6.1. QC Result analysis

QC results can be sent to the LIMS and can be processed for further analysis in lab's own Quality Control data system. Authorised staff should identify and differentiate acceptable/unacceptable random errors and trends and/or shifts in systematic errors from the statistical data. Depending on the users Quality Control Procedures analytical results could be accepted or rejected.

Changes in QC results can be gradual or abrupt. Gradual changes can be caused by contamination and incidental environmental variations. Abrupt changes can be caused by change of QC material batch or possible hardware errors.

If results are continuously out of range due to significant difference between calculated mean and control value, but the statistics show precise results with small deviations, it should be considered to expand the acceptable assay range with **QC Settings** (on page 42).

If results are incidentally out of range it is advised to perform a daily maintenance and/or End-of-day wash and then perform another QC sample step before releasing patient results.

It depends on the general QC procedure of the Lab if it is allowed to perform patient samples after the warning "CONTROL OUT OF RANGE!".

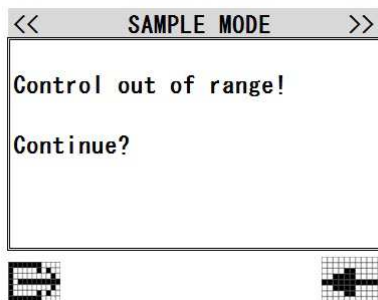
### 9.6.2. QC Error messages

The general ESR errors and warnings are also applied on the QC results, see "ESR Error and Warning code messages"

When the result is within range, no message is shown. When the result is out of range an error message is shown.



Press ESC to continue.



Press ESC to keep this warning active, press Enter to ignore this warning.

Message when the general setting "Temperature Correction" (TCorr) is switched ON:

- "E141"  
The uncorrected and the corrected result are out of range.

Messages when the general setting "Temperature Correction" (TCorr) is switched OFF:

The software always calculates a temperature corrected result because only temperature corrected results can be compared with the Assay mean value.

- "E141"  
The uncorrected and the corrected result are out of range.
- "E142"  
The uncorrected result is out of range, but the corrected result is within range.
- "E143"  
The uncorrected result is within range, but the corrected result is out of range.

See also **Quality control trouble shooting** (on page 87).

The message "CONTROL OUT OF RANGE!" will be shown until a correct QC result is performed or this message is ignored (with continue). When this warning is kept "active" no patient samples can be performed. Depending on the users Quality Control Procedures patient samples can be or cannot be performed after a QC Error message.

## 10. TURN OFF

It is recommended to turn the Starrsed Inversa off at the end of the day. Before the instrument is turned off, it is good practice to carry out the Daily maintenance or at least the End-of-day wash procedure. This will help to keep the instrument clean and almost free of bacterial growth for a period of days.

### **W A R N I N G!!!**

**Always be aware of the dangers of infection, especially during maintenance. Take the appropriate precautions.**

### 10.1. End-of-day-wash procedure

The purpose of this function is to clean the inside of the pipettes from residue which may have accumulated over time.

In the Main Menu use the function END\_OF\_DAY WASH. This function takes ca. 30 minutes to complete.

All pipettes are automatically filled with X-Clean. When the last pipette was filled, the pipettes are emptied again.

The function may be aborted by pressing the [ **CANCEL** ] key.



#### **NOTE:**

If the function was aborted, the X-Clean may not have had enough opportunity to soak and clean the pipettes.

## 11. WASTE DISPOSAL

The waste container has a level sensor and as soon as the level sensor generates a waste error, the waste container must be emptied. The waste must be treated as potentially infectious (biohazardous) material and disposed of according to local regulations. Preferably, discard the complete waste container and replace it with a cleaned one. Press **[ESC]** to clear the error.



---

**Disclaimer:** Check your local environment rules about discharging the waste.

---

### 11.1. Waste container

1. Unscrew the cap:



2. Lift the slider and take the waste container out of the compartment:



3. Close the container with the provided cap.
4. Install the empty container in the reversed order.
5. **Only for instruments with waste sensor BANG019015 :** In case of a new waste bottle: Check the values of the waste sensor at Menu "Set waste sensor".


**Warning:**

The waste must be treated as potentially infectious (biohazardous) material.


**NOTE:**

If you are re-cycling the waste container, make sure that it is bleached and rinsed thoroughly. Use only a waste container supplied by Mechatronics.

---

## 12. REPORTING

The standard output form of the Starrsed Inversa is a printed report.

The Starrsed Inversa is also able to handle different types of protocols for communication with a HOST. Communication can be bidirectional and unidirectional.

### 12.1. Protocols

A protocol is a set of rules governing the communication and the transfer of data between machines, as in a computer system. It is also a formal set of rules and procedures to be followed during a request for information before data is transferred between machines and computer systems.

The following protocols can be selected for data transfer to the Laboratory data processor computer.

1. No Serial output
2. MECHATRONICS-01 bidirectional
3. MECHATRONICS-02 unidirectional
4. Compact bidirectional
5. Compact unidirectional
6. Protocol Sysmex R-3500
7. Protocol Sysmex R-3500 unidirectional

The protocol can be set in menu SETTINGS - PROTOCOL. After selecting a protocol, save the new settings by pressing the [ **ENTER** ] key.

	CHECKSUM	ACK/NACK	30 MINUTE OUTPUT
<b>Serial 2</b>	Not selectable	Not selectable	Not selectable
<b>Serial 3</b>	Not selectable	Selectable	Not selectable
<b>Serial 4</b>	Selectable	Not selectable	Selectable
<b>Serial 5</b>	Selectable	Selectable	Selectable

## 12.2. Result Printout

The results of the ESR measurements are sent to the built-in printer and printed on thermal paper.

The layout of the report depends on the selection of the 60- or 30-minute method.



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**NOTE:**

Thermal paper is sensitive to light and printouts will start to fade after several weeks. If you need to retain the printed reports for future reference, store the printouts in a cool, dark place or make copies on a regular copy machine.

---



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**NOTE:**

The descriptions "Line 1" to "Line D" in the following subsections are only for reference within this documentation. These descriptions do not appear on the printout.

Which lines are actually displayed on the printout depends on the instrument settings and the printed result.

---

### 12.2.1. Report 60-Minute mode

	Column 1	Column 2	Column 3	Column 4
Line 1	ID	123456789 0		
Line 2	ESR T. corr		75	mm/1H
Line 3	ESR 60:		84	mm/1H
Line A	Aspect	Clear		
Line B	EDTA:	ON	ESR time	60
Line C	15-03-10	13:01	23 °C	P15
Line D				

Patient number. 1234567890

Line 1	ID	1234567890		
--------	----	------------	--	--

60-minute ESR result in millimeters, corrected for **18°C**. (only in use if temperature correction is active).

Line 2	ESR T. corr		75	mm/1H
--------	----------------	--	----	-------

Not corrected 60-minute ESR result.

Line 3	ESR 60:		84	mm/1H
--------	---------	--	----	-------

Aspect (clear, hazy).

Line A	Aspect	Clear		
--------	--------	-------	--	--

EDTA mode is On or OFF

Line B	EDTA:	ON	ESR time	60
--------	-------	----	----------	----

ESR TIME: Actual sedimentation time in minutes.

Line C	15-03-10	13:01	22 °C	P15
	The present date	Present time	Present temperature	Pipette number, in this example pipette 15

Line D is used for error and warning messages and printed in reversed colours.

### 12.2.2. Report 30 Minute mode

	Column 1	Column 2	Column 3	Column 4
Line 1	ID		123456789 0	
Line 2	ESR T. corr		75 mm/1h	
Line 3	ESR 60:		84 mm/1h	
Line 4	ESR 30:		42 mm/½h	
Line A	Aspect		Clear	
Line B	EDTA:	ON	ESR time	30
Line E	15-03-10	13:01	23 °C	P15
Line D				

Patient number.

Line 1	ID	1234567890
--------	----	------------

60-minute ESR result in millimeters, corrected for 18°C. (only in use if temperature correction is active).

Line 2	ESR T. corr	75 mm/1H
--------	----------------	----------

Not corrected 60-minute ESR result.

Line 3	ESR 60 :	84 mm/1h
--------	----------	----------

Not corrected 30-minute ESR result (only in use if 30 minute mode is active).

Line 4	ESR 30 :	42 mm/½h
--------	----------	----------

Aspect (clear, hazy).

Line A	Aspect	Clear
--------	--------	-------

EDTA mode is On or OFF

Line B	EDTA:	ON	ESR time	30
--------	-------	----	----------	----

ESR TIME: Actual sedimentation time in minutes.

Line C	15-03-10	13:01	22 °C	P15
	The present date	Present time	Present temperature	Pipette number, in this example pipette 15

Line D is used for error and warning messages and printed in reversed colours.

### 12.2.3. Analyser ERROR

Error messages can be found on the printout at the bottom line in reversed colours.  
All other lines of the report are removed accept the line with patient ID, and line B and C.

If errors are found during the measurement, the Starrsed Inversa will give an audible alarm.

### 12.2.3.1.ESR Error and Warning code messages

No errors		
No cells / plasma found	Error	No contents could be detected in the pipette.
ESR Probably >140 mm	Error	Extremely high ESR value.
Too many borders found	Error	More than three borders found, possibly air bubbles.
Fill Error	Error	Air detected below blood column.
Column height <nnn>	Warning	Column height must be between 180 and 210mm. <nnn> = the actual column height.
Measure error	Warning	The down count is not equal to the up count from the measure head.
Bubbles on top	Warning	Air bubbles on top of the ESR.
Limit error	Error	One of the following limits are out of the setting range: <ul style="list-style-type: none"> <li>• ESR Time</li> <li>• Column height</li> </ul>

#### 12.2.4. Results at limit errors

When this option is set to YES and this limit error occurs, results will be printed/send to the LIMS.

When this option is set to NO and this limit error occurs, the fields for *30 min ESR*, *60 min ESR* and the *temperature corrected ESR* are filled with spaces and thus results are not printed/send to the LIMS.

The error message in the error field (line D) indicates that at least one of the limits (ESR time, dilution rate or column height) has been exceeded.

Together with the sedimentation time and dilution rate (which are still printed at the usual position), the operator/analyst can see what caused the error and may or may not use the ESR values which are preserved in the error message.

Description of the error message **L\_err(hhh/www/ttt/ccc)** :

- **L\_err** means it is a "limit error"
- **hhh** is the 30 minutes ESR
- **www** is the 60 minute ESR
- **ttt** is the temperature corrected 60 minute result
- **ccc** is the column height

Example of a limit error message:

- **L\_err( 42/ 84/ 75/200)** means 42 mm in the 30 minute method and temperature correction 75 with a correct column height.
- **L\_err(---/ 84/ 75/200)** means 84 mm in the 60 minute method and temperature correction 75 with a correct column height.



**NOTE:**

The diluter is mechanically linked with the pipette plunger in the Starrsed Inversa. The dilution rate is therefore always 100% and will never be out of limits.

#### 12.2.5. Reporting range

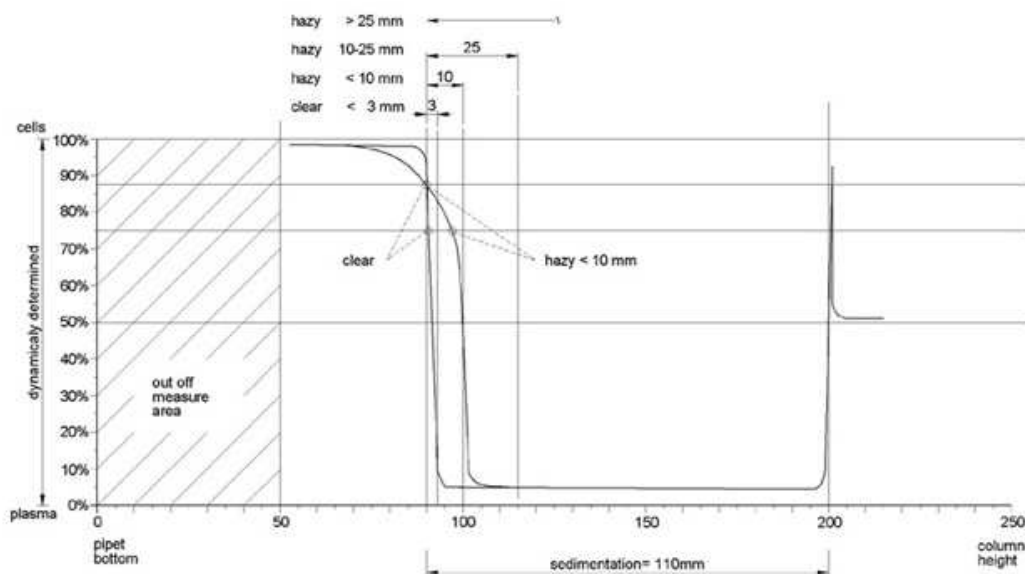
The reporting range in the lines 2, 3 and 4 are in millimeters. The start of the measure range is at the top of the meniscus down to 140 mm. If the detection of cells/plasma is over 140 mm then the report will be >140.

### 12.2.6. Aspect Hazy

The automatic reading of the Westergren sedimentation pipettes is carried out by moving an optical sensor along the pipettes. While the sensor is moving, a reading is made every 0.25 mm. The sensor is reading the absorption of infra red light through the Westergren pipette filled with blood. From these readings, values at a number of absorption levels are determined. All absorption figures are relative to the darkest and lightest reading (darkest = 100 % and the lightest = 0 % absorption respectively).

By definition the levels are:

87.5%	Cells/ plasma separation
75.0%	Hazy detection
50.0%	Meniscus detection



Graphic showing typical absorption values of a sample

The 'sedimentation' value is the distance in millimeters between the cells/plasma level (87.5% absorption) and the meniscus. If there is no haze, the absorption drops quickly to a value below the 75% level. If the distance between the 87.5% and the 75% level is less than 3mm, the report will state 'CLEAR'. If the distance between 87.5% and 75% level is more than 3mm then the report will state 'HAZY'.

Depending on the length of the 'hazy' area, three classes of 'haziness' are reported,

Length of area		Reported class	
Hazy area	>25 mm	Hazy	>25 mm
Hazy area	>10 mm <25 mm	Hazy	<25 mm
Hazy area	>3 mm < 10 mm	Hazy	<10 mm
Hazy area	< 3 mm	CLEAR	<3 mm

Hazy reports are shown when the change from the hazy level to the cell/plasma separation level occurs not within a given distance. The following code messages are reported in column 5.

#### 12.2.6.1. Analyser "HAZY" code messages

This code appears in the "sample data record" at line A.

The following 4 codes are defined:

0	Sample is clear.
1	Sample is Hazy < 10
2	Sample is Hazy < 25
3	Sample is Hazy > 25

## 13. INVERSA SYSTEM MESSAGES

### 13.1. System messages

During normal operation the following "**System messages**" may occur:

1. *Waiting tube*

- If a filled pipette is at the measuring position before the elapsed time has finished and the operator is ready to fill the next pipette, the *Waiting tube* message will be displayed.
- To continue the sample loading sequence the operator must wait until the pipette at the measuring position has been measured.

2. *Printer failure*

- Check paper quantity.
- Note: data will be stored in the buffer and can be printed afterwards.

3. *Reagents level empty message*

- All reagent bottles have level detectors; the display shows an error that indicates which reagent bottle(s) is (are) empty.
- Prepare new reagent as described in section Quick start-up.

4. *Waste bottle full message or No waste bottle message*

- The waste container also has a level detector. If a waste error is shown on the display, the Starrsed Inversa will stop filling and cleaning pipettes until a new or empty container has been installed. Preferably replace it with a cleaned one.
- Press [ **ESC** ] to clear the error.
- Check the values of the waste sensor at Menu Set waste sensor.



Warning:  
The waste must be treated as potentially infectious (biohazardous) material.

## 14. DATA SAFETY MANAGEMENT

All data in the Starrsed Inversa is stored in a **battery backup** memory.

This means that all raw data and results are kept, irrespective of a power failure or if the instrument is un-intentionally turned off. After the start-up procedure the software checks whether there are any ESR's still outstanding. If so, these will be carried out first. After a power failure the sedimentation time (60 or 30 min.) may be exceeded. However, the start time is saved and therefore the actual sedimentation time can be checked.

A limited amount of sample data can be stored, see Technical Specifications.

### 14.1. Power failure

If a power failure occurs it is recommended that the Starrsed Inversa is switched **OFF** by the power switch. When the power returns, the instrument can be switched **ON**. After the standard start-up process the Starrsed Inversa will continue to process the remaining samples.

## 15. MAINTENANCE

The **Starrsed Inversa** is an analyzer that operates with considerable amounts of whole blood virtually undiluted, and stores it in a pipette for one hour. For this reason instrument maintenance is of the utmost importance.

To maintain the maximum reliability of the instrument, the maintenance procedures must be strictly followed. All procedures are based on a number of samples.

Maintenance levels	Work instruction
<b>Daily</b> (on page 80)	<b>WI-400 Daily</b> (on page 108)
<b>Weekly</b> (on page 80)	<b>WI-406 Weekly</b> (on page 109)
<b>Level 4 maintenance</b> (on page 81)	<b>WI-404 Level 4 maintenance</b> (on page 110)
<b>Level 3 maintenance</b> (on page 81)	<b>WI-403 Level 3 maintenance</b> (on page 117)
Level 1/2 maintenance	Not available, to be performed by a trained service engineer

### WARNING!!!

Always be aware of the danger of infection, especially during maintenance. Take appropriate precautions. There is blood involved and therefore a **BIO HAZARD**



### 15.1. Daily

The purpose of the daily maintenance is to keep the instrument clean and contamination as low as possible.

See work instruction **WI-400 Daily** (on page 108) for a step-by-step procedure.

### 15.2. Weekly

The purpose of the weekly maintenance is to carry out the daily maintenance and additionally check for worn components.

See work instruction **WI-406 Weekly** (on page 109) for a step-by-step procedure.

### 15.3. Level 4 maintenance

The purpose of level 4 maintenance is to carry out the daily, the weekly maintenance and additional:

- Check the waste pump tube condition. Replace the tube if it appears worn or leaking.
- Replace the Pipette sealing and the nozzle O-rings.
- Replace Needle sealing block

See work instruction **WI-404 Level 4 maintenance** (on page 110) for a step-by-step procedure.

### 15.4. Level 3 maintenance

The purpose of level 3 maintenance is to carry out the daily, the weekly and level 4 maintenance and additional:

- Replace the pump tubing
- Replace Disk filter

See work instruction **WI-403 Level 3 maintenance** (on page 117) for a step-by-step procedure.

## 16. TROUBLE SHOOTING

Occasionally small faults may cause major problems. This chapter may help to solve the most common faults and explain why a specific problem occurs.

A lot of the problems or errors are due to a lack of maintenance. Remember that this instrument operates with a considerable amount of whole blood, virtually undiluted, stores it in a pipette for one hour and then cleans pipettes for re-use. Therefore, it is important to keep to the maintenance schedules. It is recommended that trained service personnel checks and applies service to the instrument at least once a year.

### 16.1. General error procedure

Whenever an error occurs, follow the instructions given in the Error list. If no instructions are given, follow this general procedure:

1. Clear the error by pressing the [ **ESC** ] key.
2. When the error is not cleared or the error occurs again:
3. Switch the Starrsed Inversa OFF.
4. Switch the Starrsed Inversa ON.

When the error occurs again, switch OFF all units and call for service.

### 16.2. Reagents

Check the expire dates of the reagents regularly. Do not use the reagents if expired.

---

**Note:** If expired reagent has been used accidentally, the results obtained with these reagents may only be used, when the expire date was not exceeded more than 30 days.

---

DILUENT is sensitive for bacterial growth. The solution should be discarded if it becomes turbid or infected. When using the small onboard containers, clean the DILUENT container thoroughly with 10% Na-hypochlorite. Make sure that the container has been thoroughly rinsed after cleaning.

### 16.3. Column height error

When there is a column height error detected, the software assumes that a pipette is leaking and disables the future use of this pipette.

## 16.4. Sampling not allowed now

If no chip card is inserted in the card reader and the sample mode is started by pressing 1 Sample mode, the following screen is shown:



- Press [ **ESC** ] to return to the main menu.
- Insert **Q** chip card or **A** to **E** chip card.
- Press 1 Sample mode.

## 16.5. Leaking pipettes

Pipettes may be leaking if the plunger tip is worn.

### 16.5.1. Disabling a pipette

If a pipette is leaking only slightly, this may not be detected by the instrument. Individual pipettes can be disabled manually for further use until they can be replaced:

- Note the number of the leaking pipette.
- Wait until the pipette is measured and empty.
- Go to Menu **SETTINGS - EN/DISABLE PIPET** and **follow the instructions** (on page 33).

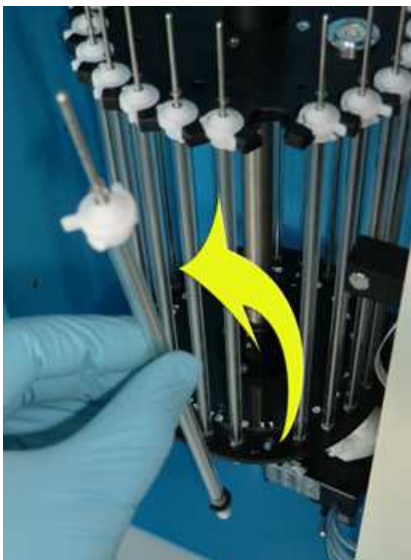
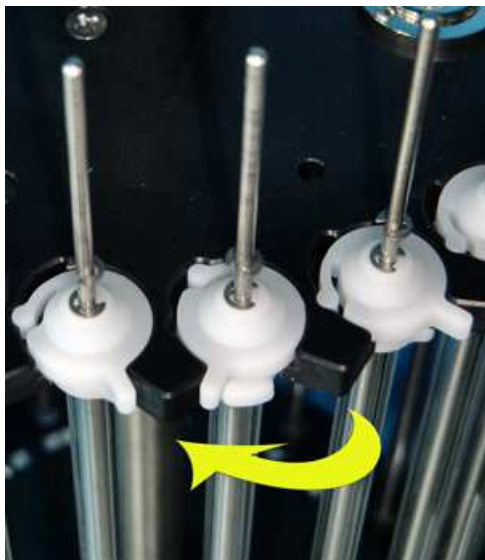
### 16.5.2. Replacing a pipette

**NOTE:** Chip card type **S** is required !



**NOTE:**  
Make sure that all pipettes are empty and do not need to be measured.

- Go to Menu SERVICE - REPLACE PIPET.
- Enter the number of the pipette to replace and press [ **ENTER** ]. The pipette is turned to the door opening.
- Open the pipette cap and lift the pipette out. Install the new pipette in the reversed order.

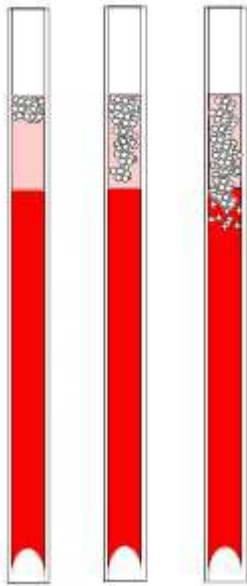


## 16.6. Air bubbles

After a normal aspiration, the Westergren pipette must be free of air bubbles. In the following examples different patterns of air bubbles which can appear in the pipettes are shown. Air bubbles can affect the sedimentation and are mostly reported as errors and no ESR result is reported.

Usually bubbles are caused by a leakage at the bottom of the pipette. If air bubbles are visible in the pipette, check the following :

### 16.6.1. Foam in column



A layer of air bubbles that is concentrated on top of the blood column does not affect the sedimentation process itself. The sedimentation develops normally below the bubbles. However, too many bubbles bring about a shortening of the effective blood column, which is a deviation from the Westergren method.

A layer of bubbles up to 5 mm: No message. Normal ESR result is reported.

A layer of bubbles from 5 to 25 mm: ESR warning 6: "Bubbles on top". Results should be reviewed before release.

A layer of bubbles larger than 25 mm: ESR Error 3: "Too many borders found". No ESR result is given.

1. Check that tube connections are not leaking.
2. Check the fill nozzle condition:
  - Inspect for any cracks or deep scratches in the base that holds the fill nozzle washer or O-ring.
3. Check for air in diluter system.

### 16.6.2. One air bubble random in pipette

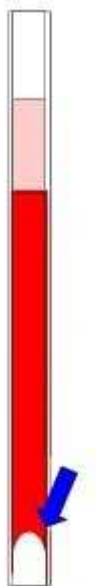


When air bubbles are seen after filling.

This can be caused during preparation of the sample. If the sample tube is, not mixed or inverted well air can arise in the blood. This causes an air bubble occurs in the pipette.

According to the ICSH, a sample should be gently inverted at least eight times. Do not shake the sample.

### 16.6.3. Large air bubble at the bottom



1. Check diluter (syringe)
2. Check Diluent bottle.
3. Insufficient or no sample volume.

A large air bubble at the bottom of the pipette results in Error 20.

## 16.7. Quality control trouble shooting

Error messages		Action	Remark/Possible cause
E140	The used Starrsed Control is out of date.	<ul style="list-style-type: none"> <li>Check expiry date.</li> </ul>	Use a new batch of Starrsed Control. Check date/time settings.
E141	Result is out of range, the applicable values for the acceptable range depend on the user setting.	<ul style="list-style-type: none"> <li>Take a new Starrsed Control sample (normal samples will be finished).</li> <li>Check acceptable range in QC settings.</li> </ul>	<p>If results are continuously out of range but the statistics show identical/stable results, it should be considered to expand the acceptable assay range with QC Settings.</p> <p>If this error persists check/clean instrument.</p>
E142	The uncorrected result is out of range, but the corrected result is within range.	<ul style="list-style-type: none"> <li>Consider QC result as correct.</li> </ul>	<p>The mean value is assayed with temperature correction, result is correct.</p> <p>Use general setting temperature correction (TCorr) ON.</p>
E143	The uncorrected result is within range, but the corrected result is out of range.	<ul style="list-style-type: none"> <li>Consider QC result as not correct.</li> <li>Take a new Starrsed Control sample (normal samples will be finished).</li> </ul>	<p>Check acceptable range in QC settings.</p> <p>If this error persists check/clean instrument.</p> <p>Use general setting temperature correction (TCorr) ON.</p>

Screen messages	Extra information	Action
QC result with ESR error	no ESR Result is given	<ul style="list-style-type: none"> <li>Check general ESR data, see ESR Error</li> <li>Check sample tube volume</li> <li>Take a new Starrsed Control sample</li> </ul>
QC result with ESR warning	ESR Result is given	<ul style="list-style-type: none"> <li>Check general ESR data, general ESR Warnings</li> <li>Check Result at limit setting</li> </ul>
CONTROL OUT OF RANGE!	This error indicates a general ESR error or a QC result error after QC sampling	<ul style="list-style-type: none"> <li>Take a new Starrsed Control sample, normal samples will be finished</li> <li>If this error persists check/clean instrument</li> </ul>

General errors	Extra information	Action
Barcode is not accepted	Barcode cannot be read  Data is incorrect	<ul style="list-style-type: none"> <li>• Check barcode</li> </ul>
QC sample is not accepted and not performed	Starred Control ID is not known in LIMS.	<ul style="list-style-type: none"> <li>• Check barcode</li> <li>• Link Starred Control ID to a Lab ID</li> </ul>
Linked Lab ID is not accepted	A Lab-ID can be linked to one Starred Control ID	<ul style="list-style-type: none"> <li>• Use another Lab ID</li> </ul>

Deviating results	Extra information	Action
Systematic QC errors with a shift in control values (QC results are out of range)	<p>The measured control values change abruptly up- or downwards.</p> <p>Do not compare 30 minute method with 60 minute method result. The calculation method can give some deviation in the general QC results statistics.</p>	<ul style="list-style-type: none"> <li>• Check/clean instrument and perform a new QC sample</li> <li>• If these errors persist perform maintenance step</li> <li>• Compare only results from one batch.</li> <li>• If Lab ID is used check the linked Starred Control ID. It is possible that a new batch is in use without changing to the new assayed mean value</li> </ul>
Systematic QC errors with a trend in control values (QC results out of the range or nearly out of the range)	The measured control values change gradually upwards or downwards.	<ul style="list-style-type: none"> <li>• Irregular or insufficient maintenance can cause unnecessary QC errors and ESR errors/warnings</li> </ul>

**Note:** QC Error messages are only shown and stored on the Starred Inversa and not send to LIMS.

QC result is given with the same general errors and warnings as a normal patient ESR-result.

## **17. APPENDIX FOR STARRSED INVERSA**

Appendix section

## Appendix - Article reference list Starrsed Inversa

The Starrsed Inversa is delivered with a complete accessories kit BANG119000. This reference list is for article order numbers only, the actual contents of the accessories kit may be changed without notice.

Part number	Description
BANG010041	Drip plate, basic
BANG020003	Plunger tip
BANG020023	Inversa service tool
BANG029002	Inversa Westergren pipette
BANG030052	Pipette sealing ring
BANG040031	Drip plate, front
BANG049002	Needle sealing block
BANG079008	Tube 8
BANG079031	Tube 31 (Only to be used for Citrate Mode)
BANG110141	Starrsed Inversa 24M User manual
QEDK100002	Euro power cable angular 90°
QEDK130501	Serial Cable SUBD9 male female
QEDV130017	Fuse 1.6 A Slow (220V)
QEDV130019	Fuse 2.5 A Slow (115V)
QEPT080100	Thermal Roll 57 x 47 x 12 mm
QWBM050014	Retaining Washer Ø 1.5 (for pipettes)
QWFG010300	Tap for Reagents container
QWLV030901	Teflon tip repair set (1 ring)
QWLV040001	Disc filter 25mm (White) (for waste container)
QWLV050003	O-ring 1.5x1 (for fill nozzle and mixing coil)
QWLV050016	O-ring 2.9x1.78 (for fill nozzle)
BANG030096	Printer paper tray
QWLV090011	Tube for peristaltic pump (24V)
QRR 010931	Diluent
QRR 010946	X- Clean
BANG31256Q	Mechatronics Instruments chip card <b>Q</b>
BANG31256S	Mechatronics Instruments chip card <b>S</b>

QWLV080002	Quad ring 3.68 x 1.78 (for valves)
BANG110021	Nozzle Calibration jig

## Appendix - Error list Starrsed Inversa

Error No.	Description	Action	Remark / Possible cause
E1	(Number not assigned)		
E2	(Number not assigned)		
E3	Carousel position error.	Set correct carousel position and/or do a "Learn positions".	Sensor value does not match with the value stored in memory. <ul style="list-style-type: none"> <li>• Carousel Position sensor malfunction.</li> </ul>
E4	Checksum error. Default RAM settings are loaded	Check settings.	Calculated checksum does not match with the checksum stored in RAM. <ul style="list-style-type: none"> <li>• Empty battery on main board.</li> <li>• RTC (DS1302) malfunction.</li> </ul>
E5	(Number not assigned)		
E6	Internal I2C communication error.		If this error occurs repeatedly, contact local service engineer.
E7	Waste bottle full.	Empty waste bottle and clear error.	<ul style="list-style-type: none"> <li>• Level sensor malfunction.</li> </ul>
E8	Warning: Diluent bottle empty.	Fill Diluent bottle.	<ul style="list-style-type: none"> <li>• Level sensor malfunction.</li> </ul>
E9	Warning: X-Clean bottle empty.	Fill X-Clean bottle.	<ul style="list-style-type: none"> <li>• Level sensor malfunction.</li> </ul>
E10	(Number not assigned)		
E11	Unknown status in cleaning routine.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.
E12	Fatal error in cleaning routine.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.
E13	Error in cleaning routine -> aborted.		If this error occurs repeatedly, contact local service engineer.
E14	(Number not assigned)		
E15	Unknown status in fill routine.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.
E16	Fatal error in fill routine.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.
E17	Fill timeout.	Check sample.	No blood detected within x seconds. <ul style="list-style-type: none"> <li>• Empty sample tube.</li> <li>• Blood detection sensor malfunction.</li> </ul>

E18	Error in fill routine -> aborted.		If this error occurs repeatedly, contact local service engineer.
E19	No sample tube detected.	Place sample tube.	<ul style="list-style-type: none"> <li>• Needle sensors malfunction.</li> </ul>
E20	Fill Error	Check diluter, diluent bottle or sample tube	<ul style="list-style-type: none"> <li>• Air detected below blood column.</li> <li>• Diluter malfunction</li> <li>• Diluter valve malfunction</li> <li>• Empty diluent bottle</li> <li>• Not enough blood in sample tube</li> <li>• Empty sample tube</li> </ul>
E21	Fill sensor error.	Check blood detection sensor.	<ul style="list-style-type: none"> <li>• Blood detection sensor out of range.</li> <li>• Check for drops of liquid.</li> </ul>
E22	(Number not assigned)		
E23	(Number not assigned)		
E24	(Number not assigned)		
E25	Filling motor could not go to home position. Gripper is closed.		<ul style="list-style-type: none"> <li>• Gripper must be open.</li> <li>• Gripper sensors malfunction.</li> </ul>
E26	Not allowed to start Filling motor. Carousel is not at a defined position.		<ul style="list-style-type: none"> <li>• Carousel home sensor malfunction.</li> </ul>
E27	Filling motor could not go down all the way. Gripper is closed.		<ul style="list-style-type: none"> <li>• Gripper must be open.</li> <li>• Gripper sensors malfunction.</li> </ul>
E28	Filling motor pulse disk error.		<p>No pulses were detected. Position of filling motor unknown.</p> <ul style="list-style-type: none"> <li>• Pulse disk malfunction.</li> <li>• Filling motor jammed or malfunction.</li> </ul>
E29	(Number not assigned)		
E30	(Number not assigned)		
E31	Carousel could not turn. Gripper is closed.		<ul style="list-style-type: none"> <li>• Gripper must be open.</li> <li>• Gripper sensors malfunction.</li> </ul>
E32	Carousel could not turn. Measure head not at home position.		<ul style="list-style-type: none"> <li>• Measuring motor home sensor malfunction.</li> </ul>
E33	Carousel could not turn. Nozzle not at home position.		<ul style="list-style-type: none"> <li>• Nozzle sensors malfunction.</li> </ul>

E34	(Number not assigned)		
E35	Not possible to open or close gripper. Carousel is not at a defined position.		<ul style="list-style-type: none"> <li>• Carousel home sensor malfunction.</li> </ul>
E36	Not possible to move the measure head. Carousel is not at a defined position.		<ul style="list-style-type: none"> <li>• Carousel home sensor malfunction.</li> </ul>
E37	Not possible to move Nozzle up or down. Carousel is not at a defined position.		<ul style="list-style-type: none"> <li>• Carousel home sensor malfunction.</li> </ul>
E38	Needle current too high.		<ul style="list-style-type: none"> <li>• Sample tube placed incorrectly.</li> <li>• Needle motor malfunction.</li> <li>• Needle motor jammed.</li> </ul>
E39	(Number not assigned)		
E40	Unknown status in measure routine.		If this error occurs repeatedly, contact local service engineer.
E41	It is not allowed to measure the pipette.		Pipette is filled with a sample but not ready for measurement.
E42	Error in measure routine -> aborted.		If this error occurs repeatedly, contact local service engineer.
E43	(Number not assigned)		
E44	(Number not assigned)		
E45	Unknown status in rotate routine.		If this error occurs repeatedly, contact local service engineer.
E46	Error in rotate routine -> aborted.		If this error occurs repeatedly, contact local service engineer.
E47	(Number not assigned)		
E48	(Number not assigned)		
E49	(Number not assigned)		
E50	Unknown status in motor initialization routine.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.
E51	Error in motor initialization routine -> aborted.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.
E52	Filling motor timeout.		<ul style="list-style-type: none"> <li>• Filling motor malfunction.</li> <li>• Filling motor jammed.</li> </ul>

E53	Needle motor timeout.		<ul style="list-style-type: none"> <li>Needle motor or sensor malfunction.</li> <li>Needle motor jammed.</li> </ul>
E54	Carrousel motor timeout.		<ul style="list-style-type: none"> <li>Carrousel motor or sensor malfunction.</li> <li>Carrousel jammed.</li> </ul>
E55	Gripper motor timeout.		<ul style="list-style-type: none"> <li>Gripper motor or sensor malfunction.</li> <li>Gripper jammed.</li> </ul>
E56	Measuring motor timeout.		<ul style="list-style-type: none"> <li>Measuring motor or sensor malfunction.</li> <li>Measure head jammed.</li> </ul>
E57	Nozzle motor timeout.		<ul style="list-style-type: none"> <li>Nozzle motor or sensor malfunction.</li> <li>Nozzle jammed.</li> </ul>
E58	(Number not assigned)		
E59	Power supply current trip.		<ul style="list-style-type: none"> <li>Check power supply.</li> </ul>
E60	(Number not assigned)		
E61	Unknown status in protocol routine.		If this error occurs repeatedly, contact local service engineer.
E62	No host response after sending request.	<ul style="list-style-type: none"> <li>Check protocol settings.</li> <li>Check LIMS settings.</li> <li>Check connection between Starrsed Inversa and LIMS.</li> </ul>	
E63	Nack received after sending request.	<ul style="list-style-type: none"> <li>Check protocol settings.</li> <li>Check LIMS settings.</li> </ul>	
E64	No host response after sending result.	<ul style="list-style-type: none"> <li>Check protocol settings.</li> <li>Check LIMS settings.</li> <li>Check connection between Starrsed Inversa and LIMS.</li> </ul>	

E65	Nack received after sending result.	<ul style="list-style-type: none"> <li>• Check protocol settings.</li> <li>• Check LIMS settings.</li> </ul>	
E66	Unknown protocol selected.	<ul style="list-style-type: none"> <li>• Check protocol settings.</li> </ul>	
E67	(Number not assigned)		
E68	(Number not assigned)		
E69	(Number not assigned)		
E70	Prime error. No diluent flow detected during priming of tube T1	<ul style="list-style-type: none"> <li>• Check diluent bottle</li> <li>• Check for leakage (pipette/nozzle)</li> <li>• Check for blockages in tubing</li> <li>• Adjust nozzle</li> </ul>	Leakage of tubing, nozzle and/or pipette Blockage/leakage in tubing causes air bubbles Incorrect nozzle adjustment Blood detection sensor malfunction
E71	Unknown status in prime routine.		If this error occurs repeatedly, contact local service engineer.
E72	Prime Diluent not allowed. Pipette not empty.		Pipette is filled with a sample. Prime is only allowed when the pipette is empty.
E73	Prime Cleaning Solution not allowed. Pipette not empty.		Pipette is filled with a sample. Prime is only allowed when the pipette is empty.
E74	Error in prime routine -> aborted.		If this error occurs repeatedly, contact local service engineer.
E75	Flash memory erased. Default settings are loaded.	Check settings.	<ul style="list-style-type: none"> <li>• Flash memory malfunction.</li> </ul>
E76	Checksum error. Default settings are loaded.	Check settings.	Calculated checksum does not match with the checksum stored in EEPROM. <ul style="list-style-type: none"> <li>• Flash memory malfunction.</li> </ul>
E77	(Number not assigned)		
E78	DS2401 not detected.		If this error occurs repeatedly, contact local service engineer. <ul style="list-style-type: none"> <li>• Serial number chip malfunction.</li> </ul>
E79	Communication error with DS2401.		If this error occurs repeatedly, contact local service engineer. <ul style="list-style-type: none"> <li>• Serial number chip malfunction.</li> </ul>

E80	SPI error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
E81	"Write mode" error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
E82	"Sector protection" error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
E83	"Pipette data" write error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
E84	"Patient data" write error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
E85	"Patient write/read index" write error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
E86	"Block erase" error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
E87	"Pipette data" erase error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
E88	"Pipette data" corrupt.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
E89	"Settings" write error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
E90	"Card & Credit data" write error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
E91	(Number not assigned)		
E92	(Number not assigned)		
E93	(Number not assigned)		
E94	(Number not assigned)		
E95	(Number not assigned)		

E96	(Number not assigned)		
E97	(Number not assigned)		
E98	(Number not assigned)		
E99	(Number not assigned)		
E100	(Number not assigned)		
E101	(Number not assigned)		
E102	(Number not assigned)		
E103	(Number not assigned)		
E104	(Number not assigned)		
E105	Unknown status in End-of-day-wash routine.		If this error occurs repeatedly, contact local service engineer.
E106	(Number not assigned)		
E107	(Number not assigned)		
E108	Unknown status in pipette test routine.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.
E109	Error in pipette test routine -> aborted.		If this error occurs repeatedly, contact local service engineer.
E110	(Number not assigned)		
E111	"ATR" error.	Remove chip card and retry.	Bad or no communication with card. <ul style="list-style-type: none"> <li>• Chip card incorrectly inserted.</li> <li>• Wrong type of chip card.</li> <li>• Chip card reader malfunction.</li> </ul>
E112	"CRC" error.	Remove chip card and retry.	Calculated CRC does not match with CRC stored in chip card memory.
E113	"Dealer code" error.	Remove chip card and insert correct card.	Dealer code does not match with dealer code set in instrument.
E114	"Card type" error.	Remove chip card and insert correct chip card.	Wrong type of chip card inserted. E.g. credit card inserted instead of service card.
E115	Card not original.	Remove chip card.	Inserted chip card is not an original Mechatronics card.
E116	"Card memory" error.	Remove chip card.	Updated chip card memory (RMA) does not match with source. Send chip card to dealer for further inspection.
E117	"Card copy" error.	Remove chip card.	Inserted chip card is a copy. Original chip card already used to upgrade credits.

E118	"Credit maximum" error.	Remove chip card.	It is not allowed to upgrade credits. Maximum of credits has been reached.
E119	"D-factor" error.	Remove chip card and change D-factor first.	It is not allowed to upgrade credits. <ul style="list-style-type: none"> <li>• D-factor must be between 1 and 10.000 when A to E chip card is used.</li> <li>• When Q-card is used D-factor must be 0.</li> </ul>
E120	"Transfer" error.	Try again or use correct chip card.	Software failed to transfer credits from or to a service card. <ul style="list-style-type: none"> <li>• Infinite credits can not be transferred.</li> <li>• Only service cards can be used to transfer credits.</li> <li>• Communication error with service card. Try again or use other service card.</li> </ul>
E121	(Number not assigned)		
E122	(Number not assigned)		
E123	(Number not assigned)		
E124	(Number not assigned)		
E125	(Number not assigned)		
E126	(Number not assigned)		
E127	(Number not assigned)		
E128	(Number not assigned)		
E129	(Number not assigned)		
E130	Internal error		If this error occurs repeatedly, contact local service engineer.
E131	Internal error		If this error occurs repeatedly, contact local service engineer.
E132	Internal error		If this error occurs repeatedly, contact local service engineer.
E133	Internal error		If this error occurs repeatedly, contact local service engineer.
E134	Internal error		If this error occurs repeatedly, contact local service engineer.
E135	(Number not assigned)		
E136	(Number not assigned)		

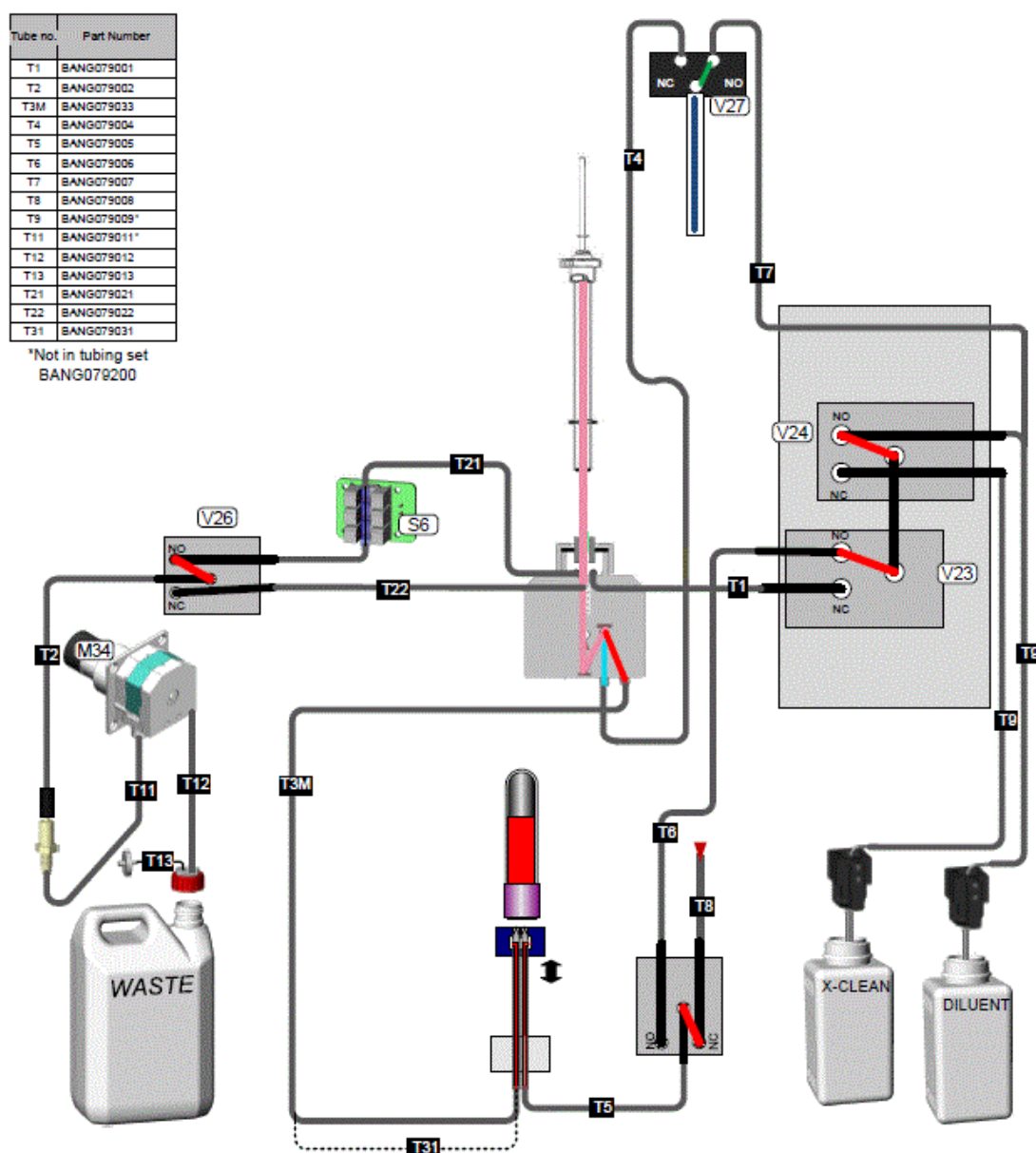
E137	(Number not assigned)		
E138	(Number not assigned)		
E139	(Number not assigned)		
E140	The used Starrsed Control is out of date.	<ul style="list-style-type: none"> <li>Check expiry date.</li> </ul>	Use a new batch of Starrsed Control. Check date/time settings.
E141	Result is out of range, the applicable values for the acceptable range depend on the user setting.	<ul style="list-style-type: none"> <li>Take a new Starrsed Control sample (normal samples will be finished).</li> <li>Check acceptable range in QC settings.</li> </ul>	<p>If results are continuously out of range but the statistics show identical/stable results, it should be considered to expand the acceptable assay range with QC Settings.</p> <p>If this error persists check/clean instrument.</p>
E142	The uncorrected result is out of range, but the corrected result is within range.	<ul style="list-style-type: none"> <li>Consider QC result as correct.</li> </ul>	<p>The mean value is assayed with temperature correction, result is correct.</p> <p>Use general setting temperature correction (TCorr) ON.</p>
E143	The uncorrected result is within range, but the corrected result is out of range.	<ul style="list-style-type: none"> <li>Consider QC result as not correct.</li> <li>Take a new Starrsed Control sample (normal samples will be finished).</li> </ul>	<p>Check acceptable range in QC settings.</p> <p>If this error persists check/clean instrument.</p> <p>Use general setting temperature correction (TCorr) ON.</p>

## Appendix - Warning list Starrsed Inversa

Wrng No.	Description	Action	Remark / Possible cause
E200	Warning: No printer.	Check printer.	<ul style="list-style-type: none"> <li>Printer malfunction.</li> </ul>
E201	Warning: Printer cover open.	Close cover.	<ul style="list-style-type: none"> <li>Cover open.</li> <li>Cover sensor malfunction.</li> </ul>
E202	Warning: Out of paper.	Put in a new paper roll.	<ul style="list-style-type: none"> <li>Out of paper.</li> <li>Paper sensor malfunction.</li> </ul>
E203	Warning: Temperature problem.	Turn off printer.	Contact local service engineer. <ul style="list-style-type: none"> <li>Print head too hot.</li> <li>Printer malfunction.</li> </ul>
E204	Warning: Power supply problem.		<ul style="list-style-type: none"> <li>Voltages out of range.</li> <li>Power supply malfunction.</li> </ul>
E205	Warning: printer buffer full.		If this error occurs repeatedly, contact local service engineer. <ul style="list-style-type: none"> <li>Printer too slow.</li> </ul>
E206	(Number not assigned)		
E207	(Number not assigned)		
E208	(Number not assigned)		
E209	(Number not assigned)		
E210	Warning: Not possible to rinse. Needle not in up position.		It is not possible to start rinsing, needle might be in sample tube. <ul style="list-style-type: none"> <li>Needle unit malfunction.</li> </ul>
E211	Warning: Last prime too long ago.	Prime system.	Last prime more than 12 hours ago.
E212	Warning: Last sample too long ago.	Start End_of_day wash.	Last sample more than 12 hours ago. Clean system.
E213	(Number not assigned)		
E214	(Number not assigned)		
E215	Low credits.	Upgrade credits.	Warning: less than 5% credits left.
E216	(Number not assigned)		
E217	(Number not assigned)		
E218	(Number not assigned)		
E219	(Number not assigned)		

## Appendix - Tube connection Starrsed Inversa

### BANG Tubing Overview



## Appendix - Default settings Starrsed Inversa

Menu text	Setting Menu	Software Default Setting	Factory Setting	Client settings
30 MIN. METHOD	Lab supervisor	OFF	OFF	
EDTA MODE	Lab supervisor	ON	ON	
TEMPERATURE	Lab supervisor	room temperature	room temperature	
Set T.CORR.	Lab supervisor	ON	ON	
Set DST	Lab supervisor	OFF	OFF	
Set RESULT AT LIMIT	Lab supervisor	ON	ON	
PRINTER (RESULTS)	Lab supervisor	ON	ON	
Set system DATE / TIME	Lab supervisor	00.00.00	Time	
Set system DATE / TIME	Lab supervisor	01-01-1998	Date	
Select LANGUAGE	Lab supervisor	English	English	
Adjust temp. Sensor	Lab supervisor	18.3	18.3	
ESR TIME (MIN)	Lab supervisor	60 Min	60 Min	
PROTOCOL	Lab supervisor	NO SERIAL OUTPUT	NO SERIAL OUTPUT	
Set BAUDRATE	Lab supervisor	9600	9600	
30 MINUTE OUTPUT	Lab supervisor	OFF	OFF	
CHECKSUM	Lab supervisor	OFF	OFF	
ACK/NACK	Lab supervisor	OFF	OFF	
BARCODE READER	Service	Keyence	Keyence	
MAX.NEEDLE CURRENT	Service	180	180	
SET PISTON POSITION	Service	900	890	

**Note:** Software Default Settings are the values that are set when the software is reset by using the key board function FACTORY SETTINGS.



## Appendix - Maintenance schedule Starrsed Inversa

Maintenance schedule Starrsed Inversa				Daily	Once a week	Level 4	Level 3	Level 2	Level 1	Total amount / year
Sample volume <200 Per day										
Daily Sample volume 150										
			Clean outside of the aspiration needle	1						
			End-of day-wash procedure / Wash all pipettes	1						
Check			Check blood sensor 110-160		1					
Check			Measure sensor 40-60 (air value)		1					
Check			Inspect sample needle condition		1					
Check			Check waste tube condition			1				
Replace			Replace nozzle O-ring and pipette sealing ring			1				
Replace			Replace needle sealing block			1				
Replace			Replace disk filter				1			
Replace			Replace waste tube				1			
Based on	750	Nozzle cleaning		every	7	days				

Appendix for **Starrsed Inversa**

Article number	Article description	Daily	Once a week	Level 4 30 days	Level 3 90 days	Level 2 180 days	Level 1 365 days	
QWLV050016	O-ring 2.9x1.78 (Nozzle)			X				12
QWLV050004	Pipette sealing ring			X				12

## **18. WORK INSTRUCTION STARRSED INVERSA**

Work instruction section

**Work instruction Number 400**
**Page 1 of 1**
**Purpose::** Daily maintenance

**Safety:** *Bio Hazard area*
**Instrument:** Starrsed Inversa

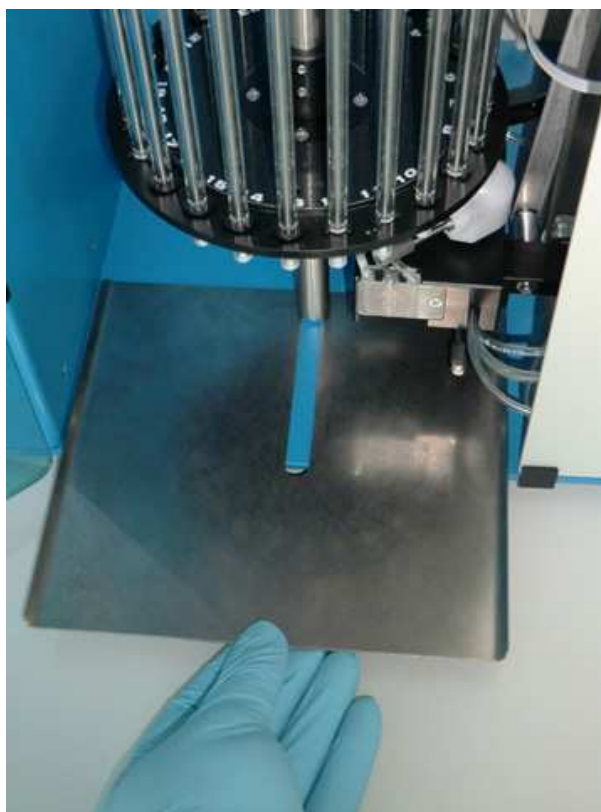
**Revision:** Draft, September 2010

**Prepare disinfectant:** (if not already prepared).

Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**

This disinfectant is for cleaning of all external parts that are exposed to blood.

1. Wipe the lower tube holder of the needle unit.
2. Wipe the stainless steel drip plates below the pipette carousel and needle unit.



3. In the Main menu use the function [END\_OF\_DAY WASH] .
4. Check the system for leakage.

**Work instruction Number 406**
**Page 1 of 1**
**Purpose:** Weekly maintenance

**Safety:** Bio Hazard area

**Instrument:** Inversa

**Revision:** 001, November 2012

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**NOTE:** Chip card type **S** is required !

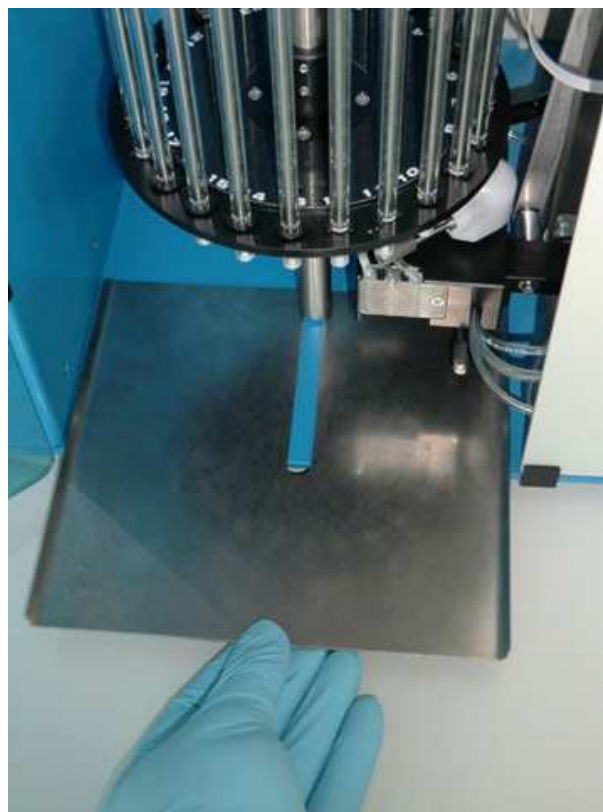
---

**Prepare disinfectant:** (if not already prepared).

Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**

This disinfectant is for cleaning of all external parts that are exposed to blood.

1. Wipe the lower tube holder of the needle unit.
2. Wipe the stainless steel drip plates below the pipette carousel and needle unit.



3. In the Main menu use the function [END\_OF\_DAY WASH] .
4. Check the system for leakage.
5. Inspect sample needle condition:  
Menu SERVICE - MOTOR CONTROL - NEEDLE M31 Press [ **ARROW DOWN** ] twice to expose the needle tips. If the tips are worn, replace the needle.

**Work instruction Number 404**
**Page 1 of 6**
**Purpose::** Level 4 maintenance

**Safety:** *Bio Hazard area*
**Instrument:** Starrsed Inversa

**Revision::** 003, December 2014

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**NOTE:** Chip card type **S** is required !

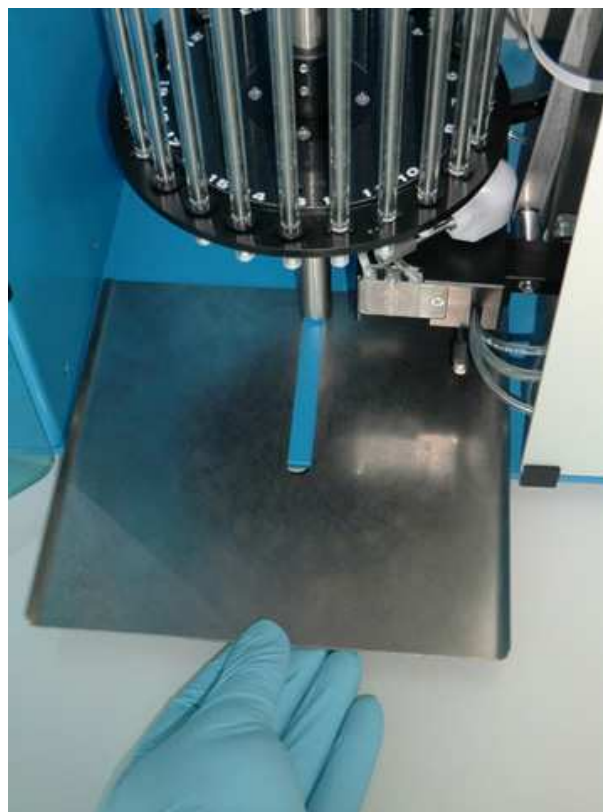
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**Prepare disinfectant:** (if not already prepared).

Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**

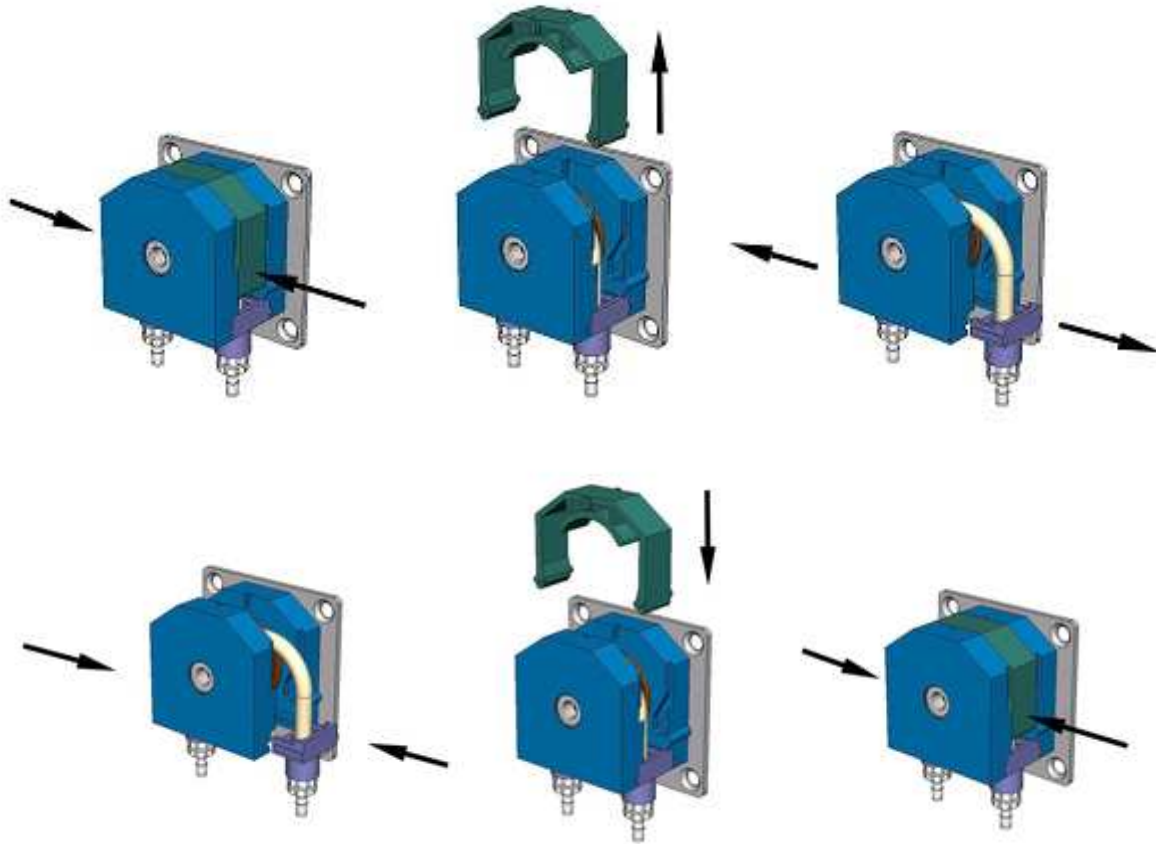
This disinfectant is for cleaning of all external parts that are exposed to blood.

1. Wipe the lower tube holder of the needle unit.
2. Wipe the stainless steel drip plates below the pipette carousel and needle unit.



3. In the Main menu use the function [END\_OF\_DAY WASH] .

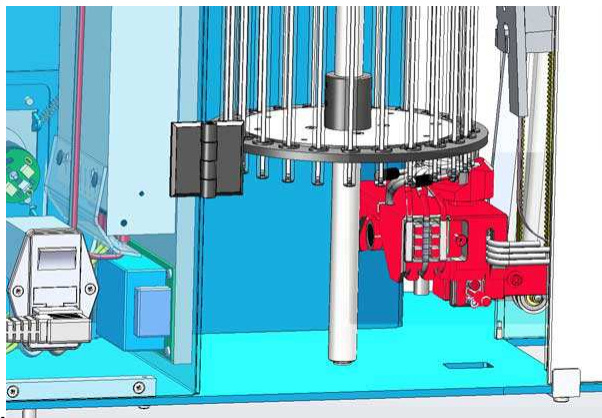
4. Check the system for leakage.
5. Check the waste pump tube condition. Replace the tube if it appears worn or leaking.



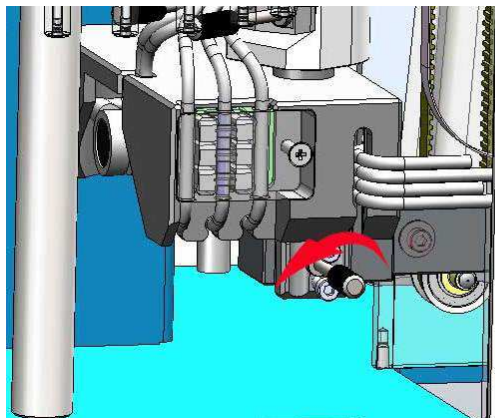
6. Inspect sample needle condition:  
Menu SERVICE - MOTOR CONTROL - NEEDLE M31 Press [ **ARROW DOWN** ] twice to expose the needle tips. If the tips are worn, replace the needle.

## Nozzle O-ring and pipette seal ring Replacement

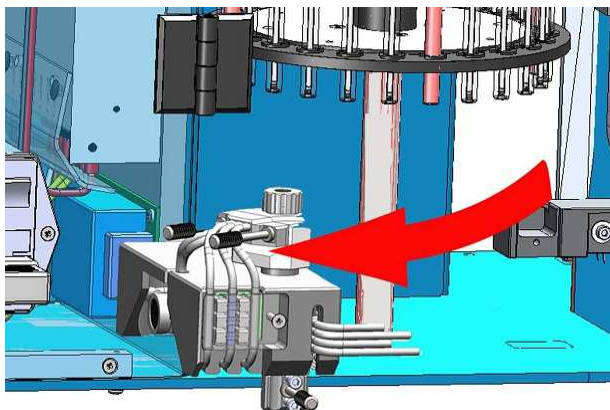
1.



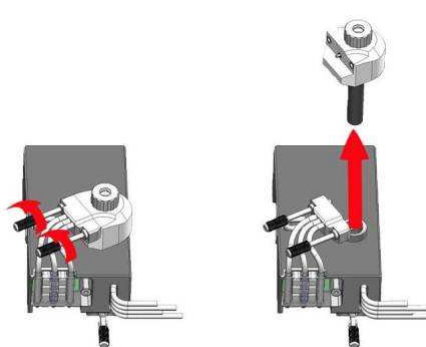
2.



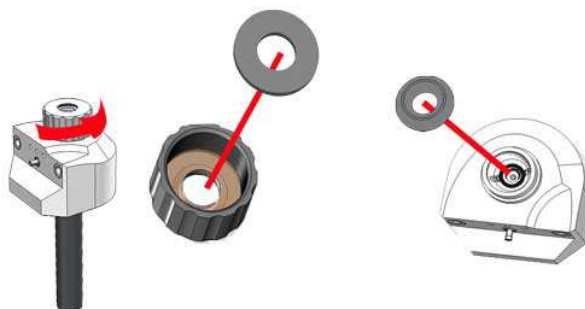
3.



4.

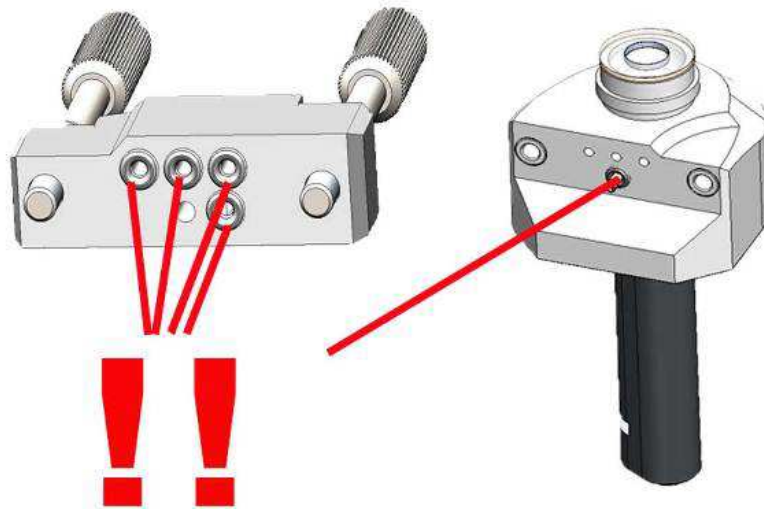


5.



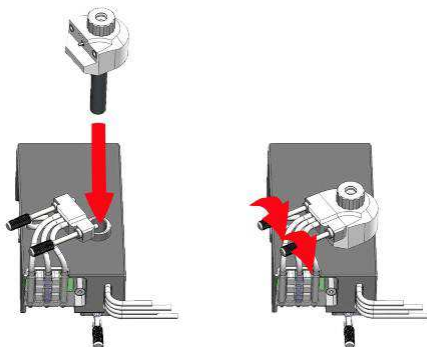
**Note:** Replace the flat pipette seal ring BANG030052 and / or replace the nozzle O-ring QWLV050016

6.

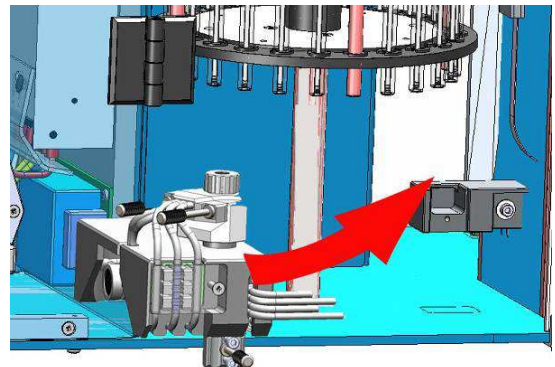


**Note:** Check if all 5 O-rings QWLV050003 are in place and / or if applicable replace the O-rings QWLV050003

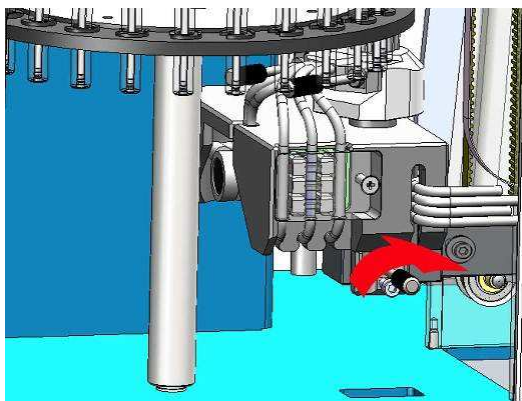
7.



8.

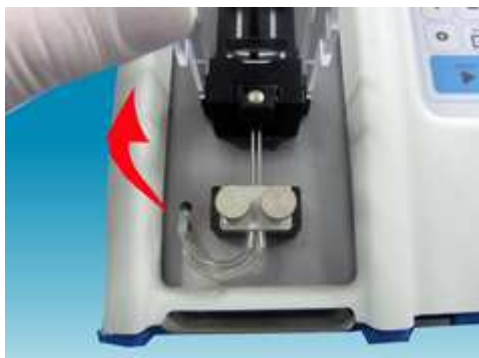


9.



## Replace Needle sealing block

Open needle cover to get access to the needle.



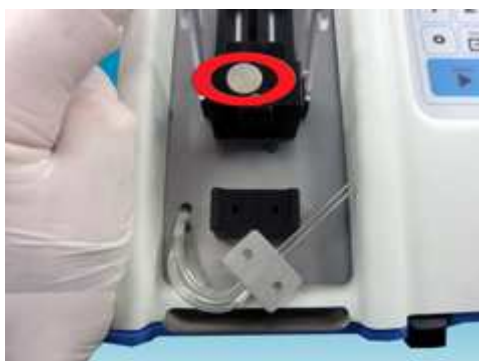
Remove both Knurled screws.



Push the needle down (friction possible)



Place screw in needle sealing block BANG049002.



Pull needle sealing block out the needle guide block assembly.



Remove screw



Place new Needle sealing block BANG049002.

Stick the needle in the needle sealing block on the needle not completely through.

Be careful for sting danger!!!

Be aware for biohazard



Place the needle sealing block into the needle guide block.

Push the needle back upwards against the friction.



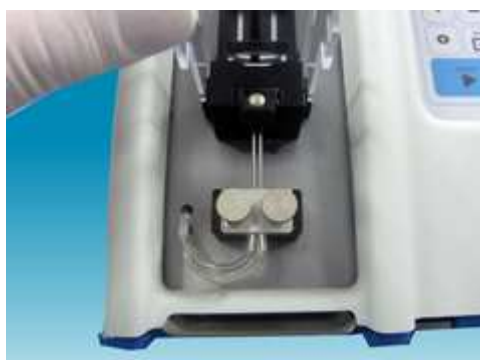
Push needle up till it is lined up to the mounting fix position.





Place both Knurled screws



Replace Needle cover.



After the assembling is finished, the needle need to be set into the correct position in the needle sealing block.

1. Insert an empty sample tube into the needle assembly.
2. Return to the main screen and go to the sample screen, type a number for the patient ID,  
press  = SAMPLING and press  
 = CANCEL key which stops the sampling.
3. The needle is now correct located in the needle sealing block.

**Work instruction Number 403**
**Page 1 of 8**
**Purpose::** Level 3 maintenance

**Safety:** *Bio Hazard area*
**Instrument:** Starrsed Inversa

**Revision::** 001, November 2012

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**NOTE:** Chip card type **S** is required !

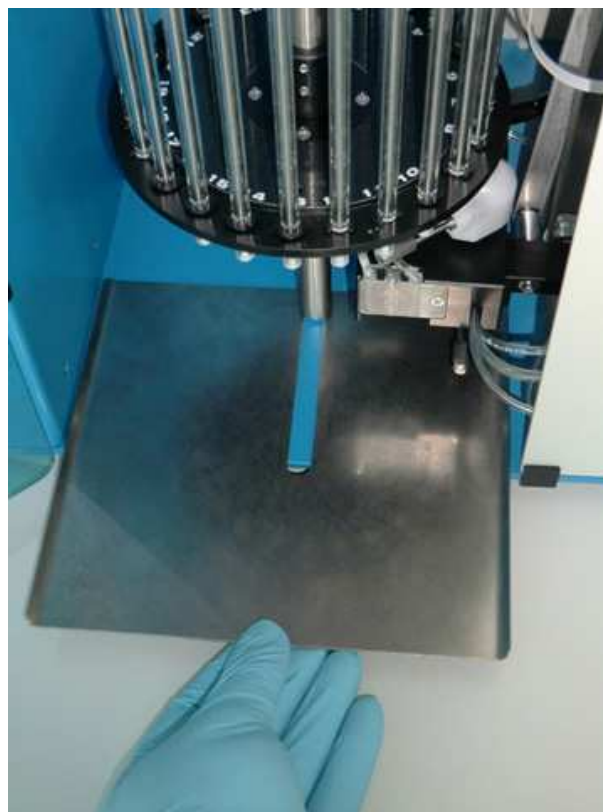
---

**Prepare disinfectant:** (if not already prepared).

Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**

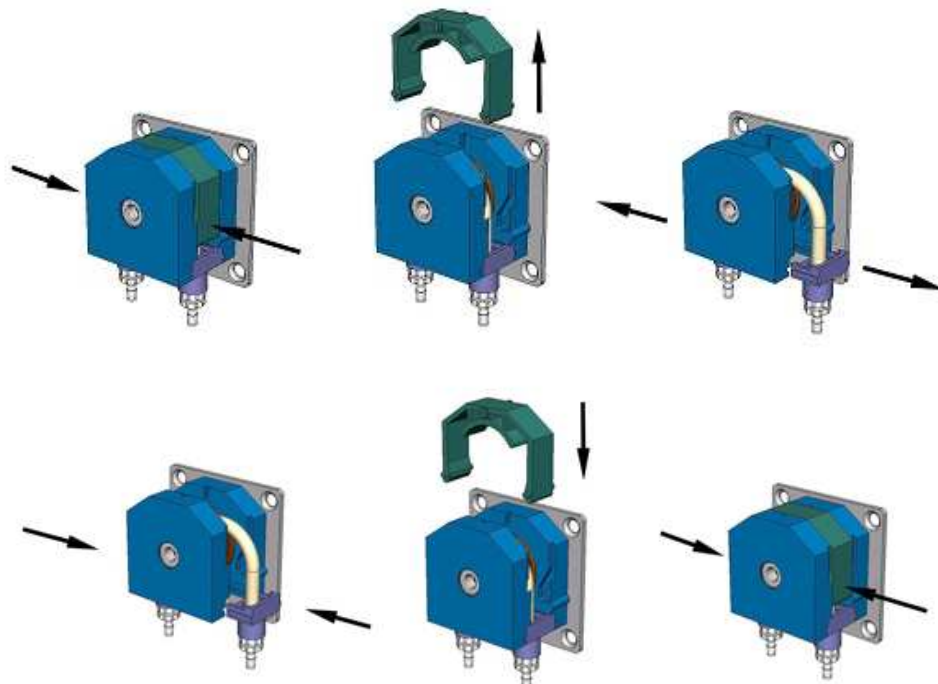
This disinfectant is for cleaning of all external parts that are exposed to blood.

1. Wipe the lower tube holder of the needle unit.
2. Wipe the stainless steel drip plates below the pipette carousel and needle unit.



3. In the Main menu use the function [END\_OF\_DAY WASH] .

4. Check the system for leakage.
5. Replace waste pump tube.

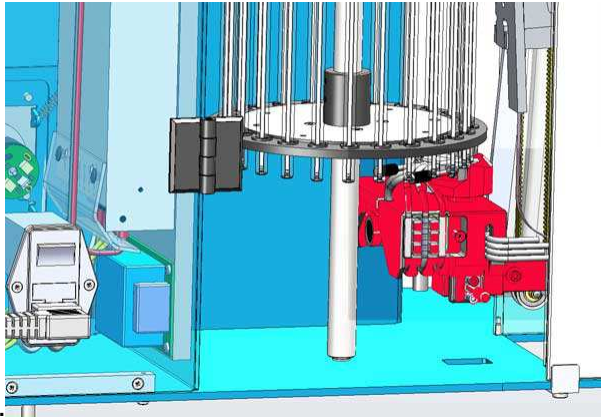


6. Inspect sample needle condition:  
Menu SERVICE - MOTOR CONTROL - NEEDLE M31 Press [ **ARROW DOWN** ] twice to expose the needle tips. If the tips are worn, replace the needle.
7. Replace disk filter  
The disk filter QWLV040001 is the filter which can be found on the waste bottle.

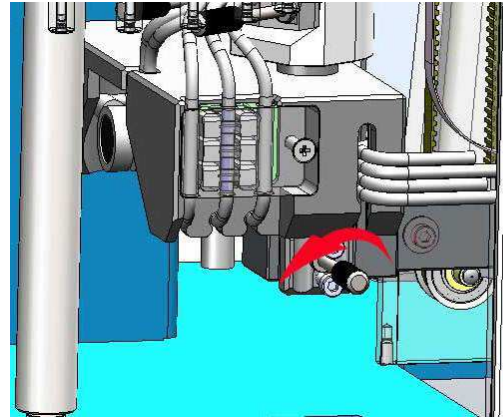


## Nozzle O-ring and pipette seal ring replacement

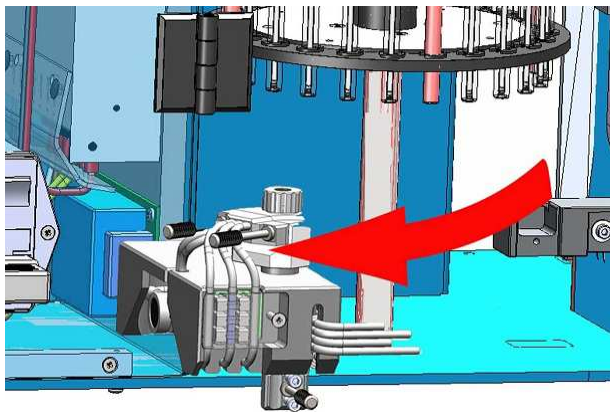
1.



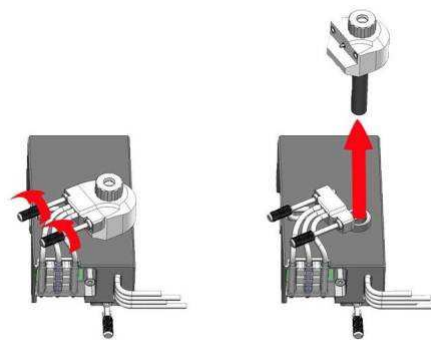
2.



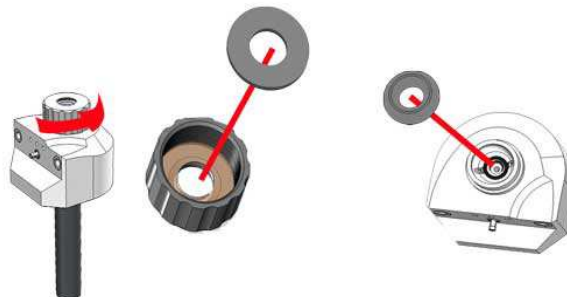
3.



4.

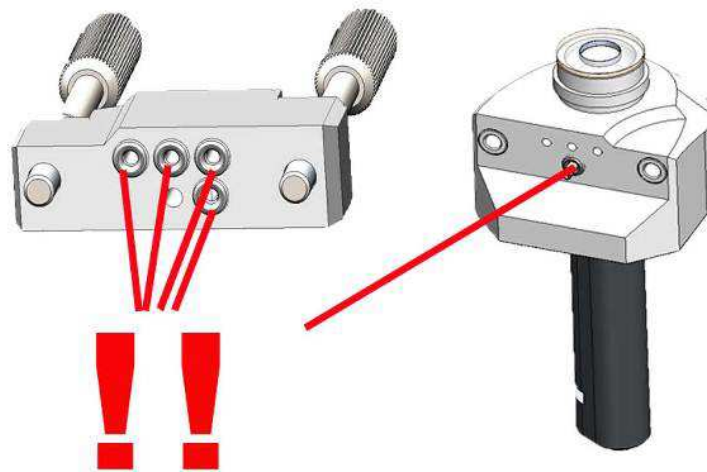


5.



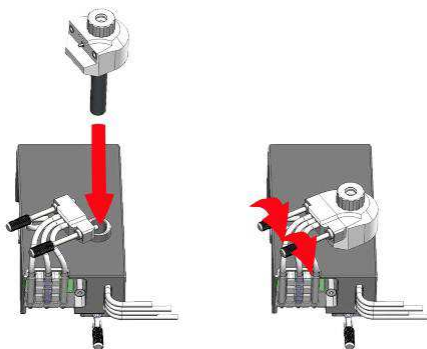
**Note:** Replace the flat pipette seal ring BANG030052 and / or replace the nozzle O-ring QWLV050016

6.

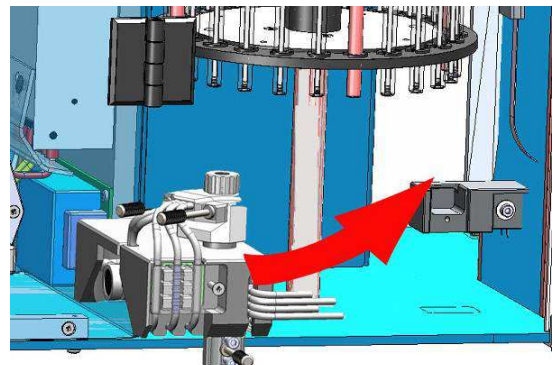


**Note:** Check if all 5 O-rings QWL050003 are in place and / or if applicable replace the O-rings QWL050003

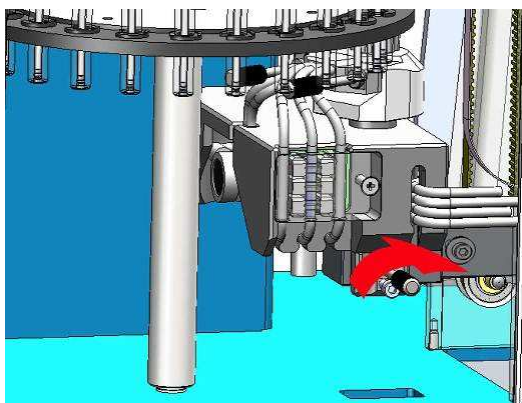
7.



8.

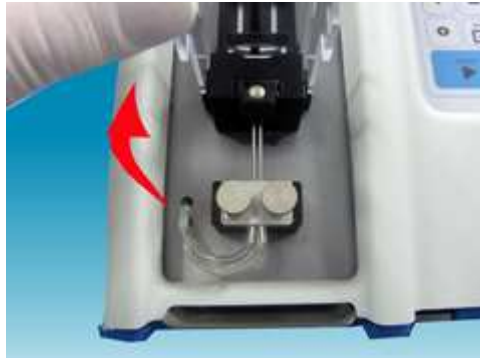


9.



## Replace Needle sealing block

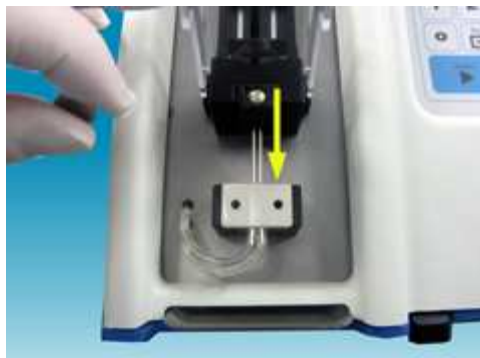
Open needle cover to get access to the needle.



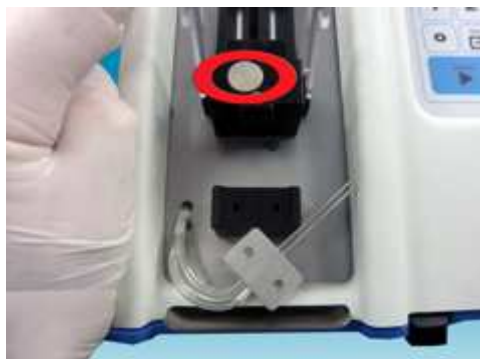
Remove both Knurled screws.



Push the needle down (friction possible)



Place screw in needle sealing block BANG049002.



Pull needle sealing block out the needle guide block assembly.



Remove screw



Place new Needle sealing block BANG049002.

Stick the needle in the needle sealing block on the needle not completely through.

Be careful for sting danger!!!

Be aware for biohazard



Place the needle sealing block into the needle guide block.

Push the needle back upwards against the friction.



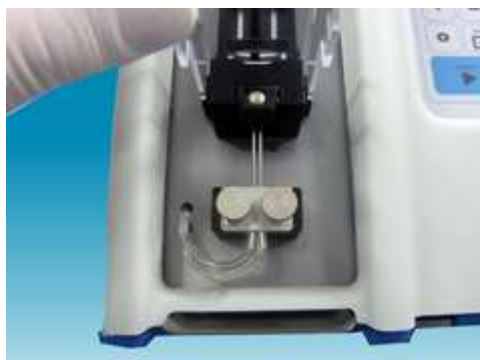
Push needle up till it is lined up to the mounting fix position.





Place both Knurled screws



Replace Needle cover.



After the assembling is finished, the needle need to be set into the correct position in the needle sealing block.

1. Insert an empty sample tube into the needle assembly.
2. Return to the main screen and go to the sample screen, type a number for the patient ID,  
press  = SAMPLING and press  
 = CANCEL key which stops the sampling.
3. The needle is now correct located in the needle sealing block.

**Work instruction Number 405**
**Page 1 of 1**
**Purpose::** Switch EDTA and Citrate mode

**Safety:** *Bio Hazard area*
**Instrument:** Starrsed Inversa

**Revision::** 001, November 2011

**NOTE:** Settings tab is password protected.  
Settings are only be changed by a Lab Supervisor.

1. Remove the front cover by lifting the clips at the top and bottom and pulling the cover away.
2. Disconnect tube with label number 3 from the needle.
3. Connect the tube with label number 31 (BANG0790031) between the tube with label number 3 and the needle.
4. Pull the added length of tubing through the stainless steel plate and store the tubing behind the plate.
5. Re-install the front cover.
6. Change settings in Menu EDTA mode: switch to the **OFF** status for using citrate blood samples.  
**ON** = EDTA mode (Tube with label number 3)  
**OFF** = Citrate mode (Tube with label number 31)

## 19. GLOSSARY OF TERMS

### B

#### 19.1.1.1.1. Bidirectional

**Bidirectional** communication means that there is two-way communication from the Starrsed Inversa to the HOST (sample requests and results) and from the HOST to the Starrsed Inversa (confirmation or denial of sample requests).

### C

#### 19.1.1.1.2. Citrate mode

**Citrate mode** is used for *pre-diluted samples* collected in tubes with *sodium citrate anticoagulant-diluent*. The samples are *not* diluted on the Starrsed Inversa during aspiration.

The concentration of sodium citrate within the diluent solution in the tube should be 3.2%. This is not to be confused with the required dilution rate of blood and diluent.

For example, in a citrate tube with a total draw volume of 1.6 ml (= 5 volumes), the amount of pre-filled diluent must be 0.32 ml (= 1 volume). If this information is not provided by the tube manufacturer, it should be checked by the customer.

### E

#### 19.1.1.1.3. EDTA mode

**EDTA mode** is used for *undiluted samples* collected in tubes with *EDTA anticoagulant*. The samples are automatically diluted on the Starrsed Inversa during aspiration. The usual amount of EDTA in sample tubes is 1.8 mg per 1 ml blood. 1 ml of blood weighs ca. 1060 mg and the concentration of EDTA is therefore 0.17% and well within the requirements for the EDTA mode on this instrument.

#### 19.1.1.1.4. ESR

**ESR** is short for **Erythrocyte Sedimentation Rate**. It is the amount of sedimentation (setting) of erythrocytes (red blood cells) in a blood column during a specified time.

### H

#### 19.1.1.1.5. Hazy

A sedimentation is reported to be "**hazy**", when the boundary between blood plasma and erythrocytes can not be defined clearly.

#### 19.1.1.1.6. Host

In this manual, the term **HOST** is used to indicate the computer system and associated software (LIMS) that provides the sample management for the laboratory.

### I

#### 19.1.1.1.7. IVD

**IVD** is short for **In Vitro Diagnostic**. This kind of diagnostic is performed on biological samples in a test tube, or more generally in a controlled environment outside a living organism. *In vitro* means *in glass* in Latin.

### M

#### 19.1.1.1.8. MRN

**MRN** is short for **Master Registration Number**. It is used as an identification number for any manual for Mechatronics products.

#### 19.1.1.1.9. MSDS

**MSDS** is short for **Material Safety Data Sheet**. In this type of MSDS all kind of important data can be found on reagents.

### T

#### 19.1.1.1.10. Temperature correction

The sedimentation of blood cells is a temperature dependent process. To achieve comparable results, **temperature correction** should always be used. The ESR results are then corrected to the value they would have been at the *standard temperature of 18.3°C*.

## U

### 19.1.1.1.11. Unidirectional

**Unidirectional** communication means that there is only one-way communication from the Starrsed Inversa to the HOST. Only sample results and result related messages are send.

## W

### 19.1.1.1.12. WI

**WI** is short for **Work Instruction** and is used with an index number for a range of work instructions.

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